

US3462091 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:38:10

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US3462091

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:41:33

Generated On: 09 Jun 2021 17:38:10

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Participant ID

US3462091

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

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US3462091

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	RIGHT EYE CATARACT
Start date (dd MMM yyyy)	UN (b) (6) 1953
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)	(b) (6) 1953
Start Year (derived)	1953
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION
Start date (dd MMM yyyy)	24 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)	29 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: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	BILATERAL KNEE DAMAGE
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	LOWER BACK RUPTURED DISCS
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	GALL BLADDER STONES
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Condition	BILATERAL LEG EDEMA
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:46 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:46
Height ( <i>xxx.x</i> )	183 cm
Weight ( <i>xxx.x</i> )	142.0 kg
BMI ( <i>xxx.x</i> )	42.40198 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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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**

PATIENT WORKS IN A CAR SHOP WITH TWO CO-WORKERS, . PATIENT HAS 3-4 CUSTOMERS PER WEEK AND WORKS 5 DAYS PER WEEK.

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PATIENT ATTEND CHURCH TWICE WEEKLY, WITH 100 OR MORE OTHER CHURCH MEMBERS.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185134

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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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)	10 AUG 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:46
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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)	10 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:50
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 10:43 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 10:43

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) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

10:31 (24 HR)

Collection date and time (derived)

10 AUG 2020 10:31

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:34	10 AUG 2020 10:34
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

10 AUG 2020 11:51

PC Open Date & Time

10 AUG 2020 11:03

PC Close Date & Time

10 AUG 2020 13:33

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	10 AUG 2020 17:04
PC Open Date & Time	10 AUG 2020 14:28
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:08

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

12 AUG 2020 18:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 17:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:15

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

15 AUG 2020 18:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

16 AUG 2020 17:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 11:52

PC Open Date & Time

10 AUG 2020 11:03

PC Close Date & Time

10 AUG 2020 13:33

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**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

10 AUG 2020 17:05

PC Open Date & Time

10 AUG 2020 14:28

PC Close Date & Time

11 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**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

11 AUG 2020 18:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**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

12 AUG 2020 18:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**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

13 AUG 2020 17:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**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

14 AUG 2020 20:15

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**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

15 AUG 2020 18:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**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

16 AUG 2020 17:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**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 ☐

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 11:53
PC Open Date & Time	10 AUG 2020 11:03
PC Close Date & Time	10 AUG 2020 13:33

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**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 ☐

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 17:05
PC Open Date & Time	10 AUG 2020 14:28
PC Close Date & Time	11 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2216

EAB) (1725)

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2216

EAB) (1725)

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 18:03
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**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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US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:03
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

58 of 2216

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:15
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

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EAB) (1725)

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 18:32
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 17:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59



US3462091

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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*

US3462091

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:23
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG



US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:42
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3462091

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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.*

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:05 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:05

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

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	10:58 (24 HR)
Collection date and time (derived)	08 SEP 2020 10:58

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:00	08 SEP 2020 11:00
Nasopharyngeal Swab 2	No		

US3462091

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**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

97.7 °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

08 SEP 2020 11:40

PC Open Date & Time

08 SEP 2020 11:25

PC Close Date & Time

08 SEP 2020 13:55

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	08 SEP 2020 18:42
PC Open Date & Time	08 SEP 2020 14:50
PC Close Date & Time	09 SEP 2020 11:59



US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**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

98.7 °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

09 SEP 2020 17:57

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

10 SEP 2020 17:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:51

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

13 SEP 2020 19:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 17:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**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

08 SEP 2020 11:40

PC Open Date & Time

08 SEP 2020 11:25

PC Close Date & Time

08 SEP 2020 13:55

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**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

08 SEP 2020 18:43

PC Open Date & Time

08 SEP 2020 14:50

PC Close Date & Time

09 SEP 2020 11:59



US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:57

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 17:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**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

11 SEP 2020 18:51

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**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

13 SEP 2020 19:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**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

14 SEP 2020 17:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**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 ☐

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:41
PC Open Date & Time	08 SEP 2020 11:25
PC Close Date & Time	08 SEP 2020 13:55



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**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 ☐

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 18:43
PC Open Date & Time	08 SEP 2020 14:50
PC Close Date & Time	09 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**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)

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 17:58
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 17:34
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**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 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:51
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:45
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 17:49
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3462091

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462091

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3462091

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

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.*

US3462091

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	07:31 (24 HR)
Collection date and time (derived)	5 OCT 2020 07:31



US3462091

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:22:44

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	14 OCT 2020 19:41:59
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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

19 OCT 2020 19:03:38

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 16:44:16
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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 22:23:18
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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	16 NOV 2020 23:07:38
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 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	25 NOV 2020 07:58:28
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 16:20:59

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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	09 DEC 2020 12:46:25
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 13:53:27
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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

23 DEC 2020 08:12:06

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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

30 DEC 2020 06:45:18

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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

06 JAN 2021 06:32:27

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 08:57:56

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 18:41:10

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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

27 JAN 2021 17:07:13

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 FEB 2021 20:38:04
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 FEB 2021 17:04:37
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 FEB 2021 18:10:43
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 09:00:04
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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

03 MAR 2021 19:17:10

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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



**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	10 MAR 2021 14:10:02
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 08:42:50

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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="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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	18 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2021 23:59
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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 SEP 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 APR 2022 23:59



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 663

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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="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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59



US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the 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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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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 <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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

**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 ☐

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

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[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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"/>

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3462091

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:38:10

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		18 MAR 2021 13:24:56

US3462091

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 00:04:29

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3462091

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 00:04:28

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 00:04:29

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 17:36:00

Generated On: 09 Jun 2021 17:38:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462091

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4



US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:36:00

Generated On: 09 Jun 2021 17:38:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 10:16
Temperature (xxx.x)	98 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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3462091

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3462091

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	15 MAR 2021 10:40

US3462091

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3462091**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

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*

**US3462091**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3462091**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:38:10**

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"/>

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3462091

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:41:34

Generated On: 09 Jun 2021 17:38:10

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

Visit date (dd MMM yyyy)	12 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
------------	---------------

US3462091

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:06:18

Generated On: 09 Jun 2021 17:38:10

Date of updated informed consent (dd MMM yyyy) 17 DEC 2020

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)

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

US3462091

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:41:34

Generated On: 09 Jun 2021 17:38:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	09:34 (24 HR)
Collection date and time (derived)	12 JAN 2021 09:34

US3462091

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:41:34

Generated On: 09 Jun 2021 17:38:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	09:22
Collection Date and Time (derived)	12 JAN 2021 09:22

US3462091

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:41:33

Generated On: 09 Jun 2021 17:38:10

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

AEID	USA-US093-2020-MRNA-1273-P30 1000007
Adverse event	NECK PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	14 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

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

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

---

PER PATIENT REPORT OVER  
PHONE ON 19OCT20 AT 13:22,  
ON 09OCT20 PATIENT HAD  
SYMPTOMS OF SEVERE  
NECK/BACK PAIN STARTING  
WITH NO KNOWN  
TRIGGER/INCIDENT. WIFE  
DROVE PATIENT TO ER AND  
PATIENT WAS HOSPITALIZED  
FOR 5 NIGHTS. PER PATIENT, 3  
SPINAL TAPS WERE DONE, AND  
AN ECOLI AND COVID TEST  
PERFORMED, AND ALL  
FINDINGS WERE NEGATIVE.  
PER PATIENT, OXYCODONE, AN  
ANTIBIOTIC, A MUSCLE  
RELAXANT AND TYLENOL  
WERE PRESCRIBED, AND  
MORPHINE GIVEN VIA IV  
FLUIDS. PATIENT WAS ON IV  
FLUIDS 10/9-10/14. PATIENT  
DOES RECALL ALL  
MEDICATION DETAILS.  
PATIENT FEELS MUCH  
IMPROVED AND LAST DOSE OF  
ANTIBIOTICS AND PAIN  
MEDICATION WAS 10/16/2020.  
MEDICAL RECORDS WILL BE  
REQUESTED FOR MORE  
DETAILS.

---

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

---



US3462091

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

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

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:41:34

Generated On: 09 Jun 2021 17:38:10

---

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

Yes ☒

No ☐

---

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

---

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE  
EXACERBATION

Dose per administration 60

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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EAB) (1725)

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US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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)	24 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 JUN 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMINARY DISEASE  
EXACERBATION

Dose per administration 20

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 (2)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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)	27 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 JUN 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication CONGESTIVE HEART FAILURE

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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 2008	
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"/>

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication CONGESTIVE HEART FAILURE

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 (5)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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 2008	
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) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication TORSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL LEG EDEMA

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 (6)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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 2008	
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 (7)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication POTASSIUM

Prophylaxis Yes ☒  
No ☐

Indication 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 (7)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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 2008	
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 (9)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication BROVANA

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMINARY DISEASE

Dose per administration 1

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

If dose unit is Other, specify NEBULIZER

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN MAY 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 (10)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication QVAR

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMINARY DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
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 (11)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication STIOLTO

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMINARY DISEASE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication JARDIANCE

Prophylaxis Yes ☐  
No ☒

Indication CONGESTIVE HEART FAILURE

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 (12)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication NECK PAIN

Dose per administration 1

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

If dose unit is Other, specify DOSE UNKNOWN

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 CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication NECK PAIN

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 (14)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication NECK PAIN

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication MUSCLE RELAXANT

Prophylaxis Yes ☐  
No ☒

Indication NECK PAIN

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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EAB) (1725)

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication	ANTIBIOTIC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NECK PAIN
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN. WAITING FOR MEDICAL RECORDS.
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input checked="" type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

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

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 22:55:08

Generated On: 09 Jun 2021 17:38:10

	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)	8 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:41:34

Generated On: 09 Jun 2021 17:38:10

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 19:41:34

Generated On: 09 Jun 2021 17:38:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 OCT 2020	SPINAL TAP	Adverse Event	
09 OCT 2020	SPINAL TAP	Adverse Event	
9 OCT 2020	SPINAL TAP	Adverse Event	
9 OCT 2020	NASAL SWAB	Adverse Event	
9 OCT 2020	ECOLI TEST	Adverse Event	
9 OCT 2020	ELECTROCARDIOGRAM	Adverse Event	
9 OCT 2020	IV FLUIDS	Adverse Event	

US3462091

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:38:10

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

US3462091

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:38:10

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 ☐

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

SAEID	USA-US093-2020-MRNA-1273-P301000007
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

SAEID	USA-US093-2020-MRNA-1273-P301000007
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/OCT/2020 16:47
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

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

SAEID	USA-US093-2020-MRNA-1273-P301000007
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/NOV/2020 06:05
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



US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

SAEID	USA-US093-2020-MRNA-1273-P301000007
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/FEB/2021 14:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 13:15:28

Generated On: 09 Jun 2021 17:38:10

SAEID	USA-US093-2020-MRNA-1273-P301000007
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	GREGG
Investigator's Last Name	LUCKSINGER
Site Address: Street	1900 CYPRESS CREEK RD
Site Address: City	CEDAR PARK
Site Address: State	TX
Site Address: Postal Code	78613
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/APR/2021 12:10
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

US3462091 (Prod: Crisor, LLC)

**US3462091**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:38:10**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'US3462091'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:34:50

**US3462091**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:28

**US3462091**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:34:52

**US3462091**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[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 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:28

**US3462091**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'SCRN'	System	10 Aug 2020 18:08:28



**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:34:53

US3462091

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:38:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	19 Oct 2020 23:53:58
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 23:53:58
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	10 Aug 2020 18:09:04
User entered '67'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'YEARS'	System	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '66'	System	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52



**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:38:10**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:08:52

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:09:04



**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Aug 2020'	System	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2020'	System	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:09:04

**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:34:52



**US3462091**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:38:10**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'I'	System	10 Aug 2020 18:09:08

**US3462091**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:09:08

**US3462091**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:38:10**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:20:05

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 11:44:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 11:44:20
Data point term sent to Coder	System	12 Aug 2020 16:21:25
User entered 'RIGHT EYE CATARACT'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	(b) (4)	19 Oct 2020 23:54:43
User entered 'UN (b) (6) 1953' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 23:54:43
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	12 Aug 2020 16:20:38
User entered 'UN UNK 1953'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:38:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

**US3462091**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

**US3462091**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:38:10**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38



**US3462091**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

**US3462091**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered (b) (6) 1953'	System	19 Oct 2020 23:54:43
User entered 'Jan 1953'	System	12 Aug 2020 16:20:38

**US3462091**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '1953'	System	12 Aug 2020 16:20:38

**US3462091**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:20:38

**US3462091**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:38:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Left cataract - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:22:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:22:08
Data point term sent to Coder	System	12 Aug 2020 16:21:26
User entered 'LEFT EYE CATARACT'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2010'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57



**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2010'	System	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2010'	System	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:20:57

**US3462091**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:38:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 13:59:00
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Conmed has been entered.' (Site from DM).		07 Nov 2020 19:09:41
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		01 Oct 2020 08:06:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:26:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:26:17
Data point term sent to Coder	System	12 Aug 2020 16:24:29
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Daniel Hamlin (b) (4)	12 Aug 2020 16:23:30



**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2015'	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2015'	System	12 Aug 2020 16:23:30

**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2015'	System	12 Aug 2020 16:23:30

**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:23:30



**US3462091**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 12:42:30
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).		19 Oct 2020 23:55:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		01 Oct 2020 08:06:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease exacerbation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:25:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:25:11
Data point term sent to Coder	System	12 Aug 2020 16:24:30
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION'	Daniel Hamlin (b) (4)	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '24 Jun 2020'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '29 Jun 2020'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jun 2020'	System	12 Aug 2020 16:24:17



**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2020'	System	12 Aug 2020 16:24:17

**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jun 2020'	System	12 Aug 2020 16:24:17

**US3462091**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2020'	System	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:36
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).		19 Oct 2020 23:55:37
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).		01 Oct 2020 08:06:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:26:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:26:23
Data point term sent to Coder	System	12 Aug 2020 16:25:32
User entered 'TYPE 2 DIABETES'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2010'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:38:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37



**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2010'	System	12 Aug 2020 16:24:37

**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2010'	System	12 Aug 2020 16:24:37

**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:24:37

**US3462091**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
Data point term sent to Coder	System	12 Aug 2020 16:25:31
User entered 'LEFT SHOULDER DAMAGE'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2013'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55



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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:38:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of LEFT SHOULDER DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 13:59:13
User entered 'No (N)' reason for change: Data Entry Error		07 Nov 2020 20:40:13
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of LEFT SHOULDER DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' answered with 'UPDATED' (Site from DM).		07 Nov 2020 20:39:59
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of LEFT SHOULDER DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).		01 Oct 2020 08:07:03
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2013' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:40:13
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2013'	System	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2013'	System	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2013'	System	07 Nov 2020 20:40:13
User entered empty.	System	12 Aug 2020 16:24:55

**US3462091**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2013'	System	07 Nov 2020 20:40:13
User entered empty.	System	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
Data point term sent to Coder	System	12 Aug 2020 16:25:32
User entered 'BILATERAL KNEE DAMAGE'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08



**US3462091**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2007'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

**US3462091**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of BILATERAL KNEE DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 13:59:20
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of BILATERAL KNEE DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' answered with 'NOTED, HOWEVER, THE CONDITION KNEE DAMAGE IS NOT THE EVENT BUT THE CONDITON OF THIS PERSON'S KNEE. THE DAMAGE IS UNREPAIRED AND STILL THERE. PLEASE CONTINUE TO ADVISE IF AN END DATE IS STILL THOUGH NECESSARY.' (Site from DM).		07 Nov 2020 20:43:52
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of BILATERAL KNEE DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).		01 Oct 2020 08:07:20
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:38:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

**US3462091**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

**US3462091**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2007'	System	12 Aug 2020 16:25:08

**US3462091**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2007'	System	12 Aug 2020 16:25:08

**US3462091**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:25:08



**US3462091**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
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 protrusion, LLT: Ruptured intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:24:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:24:20
Data point term sent to Coder	System	12 Aug 2020 16:25:32
User entered 'LOWER BACK RUPTURED DISCS'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2004'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:38:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2004'	System	12 Aug 2020 16:25:25



**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2004'	System	12 Aug 2020 16:25:25

**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:25:25

**US3462091**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallbladder stones - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:27:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:27:14
Data point term sent to Coder	System	12 Aug 2020 16:26:33
User entered 'GALL BLADDER STONES'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2008'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42



US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:38:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2008'	System	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2008'	System	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:25:42

**US3462091**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:38:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User coded data point as SOC: Cardiac disorders, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:58:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:58:50
Data point term sent to Coder	System	04 Feb 2021 17:58:26
User entered 'Congestive heart failure'	(b) (4), (b) (6)	04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'UN UNK 2008' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:18:13
User entered 'un UNK 2012'		04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:57:26



**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2008'	System	08 Feb 2021 18:18:13
User entered 'Jan 2012'	System	04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2008'	System	08 Feb 2021 18:18:13
User entered '2012'	System	04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	04 Feb 2021 17:57:26

**US3462091**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	04 Feb 2021 17:57:26

US3462091

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:38:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema legs - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 18:11:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 18:11:50
Data point term sent to Coder	System	04 Feb 2021 18:11:06
User entered 'Bilateral Leg Edema'	(b) (4), (b) (6)	04 Feb 2021 18:10:16



**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:10:16

**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:10:16

**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:10:16

**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:10:16

**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:10:16

**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'Jan 2008'	System	04 Feb 2021 18:10:16

**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '2008'	System	04 Feb 2021 18:10:16

**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	04 Feb 2021 18:10:16



**US3462091**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered empty.	System	04 Feb 2021 18:10:16

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '09:46'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

**US3462091**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered '10 Aug 2020 09:46'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '183' cm	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
Amendment Manager: User entered '42.40198'	System	16 Sep 2020 23:50:00
User entered '42.4'	System	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08



**US3462091**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'kg/m2'	System	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '97.9' F	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '71'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

**US3462091**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'bpm'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '12'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

**US3462091**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'breaths/min'	System	12 Aug 2020 16:26:35



US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '123'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

**US3462091**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'mmHg'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '74'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User entered 'mmHg'	System	12 Aug 2020 16:26:35

**US3462091**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41

**US3462091**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41

US3462091

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:26:47

US3462091

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 12:23:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:23:08
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:47



US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

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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)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08



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Folder: Screening

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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)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

**US3462091**

**Folder: Screening**

**Form: Risk of Exposure**

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**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'patient works in a car shop with two co-workers, . Patient has 3-4 customers per week and works 5 days per week.'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

**US3462091**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:38:10**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:38:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:47:41
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'patient attend church twice weekly, with 100 or more other church members.'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:11:08

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:38:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:37
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:12:34

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:12:34

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:12:34



**US3462091**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'VISIT1'	System	10 Aug 2020 18:12:37
User entered empty.	System	10 Aug 2020 18:12:34

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 17:19:23

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:10

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:18:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:18:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 17:19:23
User entered '185134' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 17:19:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:10

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 17:19:23

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:38:10

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:13:05

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:38:10**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:05

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:38:10**

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:05

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:38:10**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:05



**US3462091**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:38:10**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:22
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:40:23
User entered '183' cm	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:22
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:40:23
User entered '183' cm	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '09:46'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered '10 Aug 2020 09:46'	System	12 Aug 2020 16:27:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '97.9' F	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Tympanic' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '71'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'bpm'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '12'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25



**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'breaths/min'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '123'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'mmHg'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '74'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'mmHg'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:22
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:40:23
User entered '183' cm	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:38:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05



US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '11:50'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered '10 Aug 2020 11:50'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '98.4' F	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Tympanic' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '76'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05



**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'bpm'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '12'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'breaths/min'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '118'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'mmHg'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '76'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'mmHg'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:19



US3462091

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:19

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:44

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10:43'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:44

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered '10 Aug 2020 10:43'	System	10 Aug 2020 18:13:44



**US3462091**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 18:13:44

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'ONCE'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:45

US3462091

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:45

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10:31'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:45

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered '10 Aug 2020 10:31'	System	12 Aug 2020 16:28:45

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:38:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56



**US3462091**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:38:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10:34'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered '10 Aug 2020 10:34'	System	12 Aug 2020 16:28:56

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:38:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered empty.	System	12 Aug 2020 16:28:56



US3462091

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:38:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	12 Aug 2020 16:29:01

**US3462091**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'I'	System	12 Aug 2020 16:29:01

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:51:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125' User entered 'Yes (Y)'	System	10 Aug 2020 18:51:29
	System	10 Aug 2020 18:51:29

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:50:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125' User entered '98.4'	System	10 Aug 2020 18:51:29
	System	10 Aug 2020 18:51:29

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:50:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125'	System	10 Aug 2020 18:51:29
User entered 'No (N)'	System	10 Aug 2020 18:51:29

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:51:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125'	System	10 Aug 2020 18:51:29
User entered '10 Aug 2020 11:51'	System	10 Aug 2020 18:51:29

**US3462091**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 11:03'	System	10 Aug 2020 18:13:44



**US3462091**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 13:33'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered 'Yes (Y)'	System	11 Aug 2020 00:04:57

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered '98.7'	System	11 Aug 2020 00:04:57

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered 'No (N)'	System	11 Aug 2020 00:04:57

**US3462091**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered '10 Aug 2020 17:04'	System	11 Aug 2020 00:04:57

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 14:28'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:13:44



US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 2'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered 'Yes (Y)'	System	12 Aug 2020 01:08:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered '98.2'	System	12 Aug 2020 01:08:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered 'No (N)'	System	12 Aug 2020 01:08:59

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:57', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered '11 Aug 2020 18:08'	System	12 Aug 2020 01:08:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 3'	System	10 Aug 2020 18:13:44



US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:02:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc'	System	13 Aug 2020 01:03:10
User entered 'Yes (Y)'	System	13 Aug 2020 01:03:10

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:02:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc' User entered '98.7'	System	13 Aug 2020 01:03:10
	System	13 Aug 2020 01:03:10

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc'	System	13 Aug 2020 01:03:10
User entered 'No (N)'	System	13 Aug 2020 01:03:10

**US3462091**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc'	System	13 Aug 2020 01:03:10
User entered '12 Aug 2020 18:03'	System	13 Aug 2020 01:03:10

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 4'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:02:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e' User entered 'Yes (Y)'	System	14 Aug 2020 00:03:06
	System	14 Aug 2020 00:03:06



US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:02:53', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e' User entered '97.3'	System	14 Aug 2020 00:03:06
	System	14 Aug 2020 00:03:06

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:02:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e' User entered 'No (N)'	System	14 Aug 2020 00:03:06
	System	14 Aug 2020 00:03:06

**US3462091**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e' User entered '13 Aug 2020 17:03'	System	14 Aug 2020 00:03:06
	System	14 Aug 2020 00:03:06

**US3462091**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 5'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:14:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108'	System	15 Aug 2020 03:15:14
User entered 'Yes (Y)'	System	15 Aug 2020 03:15:14

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108' User entered '97.2'	System	15 Aug 2020 03:15:14
	System	15 Aug 2020 03:15:14



US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108'	System	15 Aug 2020 03:15:14
User entered 'No (N)'	System	15 Aug 2020 03:15:14

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108'	System	15 Aug 2020 03:15:14
User entered '14 Aug 2020 20:15'	System	15 Aug 2020 03:15:14

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 6'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f' User entered 'Yes (Y)'	System	16 Aug 2020 01:31:54
	System	16 Aug 2020 01:31:54

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f' User entered '97.9'	System	16 Aug 2020 01:31:54
	System	16 Aug 2020 01:31:54

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f'	System	16 Aug 2020 01:31:54
User entered 'No (N)'	System	16 Aug 2020 01:31:54



US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f' User entered '15 Aug 2020 18:31'	System	16 Aug 2020 01:31:54
	System	16 Aug 2020 01:31:54

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 7'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered 'Yes (Y)'	System	17 Aug 2020 00:01:30

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered '98.8'	System	17 Aug 2020 00:01:30

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered 'No (N)'	System	17 Aug 2020 00:01:30

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered '16 Aug 2020 17:01'	System	17 Aug 2020 00:01:30



**US3462091**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9' User entered 'None (1)'	System	10 Aug 2020 18:52:37
	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered 'No (N)'	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered 'No (N)'	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9' User entered 'None (1)'	System	10 Aug 2020 18:52:37
	System	10 Aug 2020 18:52:37

**US3462091**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered '10 Aug 2020 11:52'	System	10 Aug 2020 18:52:37



**US3462091**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 11:03'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 13:33'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'None (1)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'No (N)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:09', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'No (N)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'None (1)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered '10 Aug 2020 17:05'	System	11 Aug 2020 00:05:21



**US3462091**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 14:28'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 2'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b' User entered 'None (1)'	System	12 Aug 2020 01:09:23
	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b' User entered 'No (N)'	System	12 Aug 2020 01:09:23
	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b' User entered 'No (N)'	System	12 Aug 2020 01:09:23
	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b' User entered 'None (1)'	System	12 Aug 2020 01:09:23
	System	12 Aug 2020 01:09:23

**US3462091**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b' User entered '11 Aug 2020 18:09'	System	12 Aug 2020 01:09:23
	System	12 Aug 2020 01:09:23



**US3462091**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 3'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'None (1)'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'No (N)'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:17', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'No (N)'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'None (1)'	System	13 Aug 2020 01:03:32

**US3462091**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered '12 Aug 2020 18:03'	System	13 Aug 2020 01:03:32



**US3462091**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 4'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered 'None (1)'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:17', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered 'No (N)'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered 'No (N)'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:24', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee' User entered 'None (1)'	System	14 Aug 2020 00:03:31
	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered '13 Aug 2020 17:03'	System	14 Aug 2020 00:03:31



**US3462091**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 5'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0' User entered 'None (1)'	System	15 Aug 2020 03:15:31
	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered 'No (N)'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered 'No (N)'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered 'None (1)'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered '14 Aug 2020 20:15'	System	15 Aug 2020 03:15:31



**US3462091**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 6'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d' User entered 'None (1)'	System	16 Aug 2020 01:32:15
	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered 'No (N)'	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered 'No (N)'	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d' User entered 'None (1)'	System	16 Aug 2020 01:32:15
	System	16 Aug 2020 01:32:15

**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered '15 Aug 2020 18:32'	System	16 Aug 2020 01:32:15



**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 7'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b' User entered 'None (1)'	System	17 Aug 2020 00:01:53
	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b'	System	17 Aug 2020 00:01:53
User entered 'No (N)'	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:42', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b'	System	17 Aug 2020 00:01:53
User entered 'No (N)'	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b' User entered 'None (1)'	System	17 Aug 2020 00:01:53
	System	17 Aug 2020 00:01:53

**US3462091**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b' User entered '16 Aug 2020 17:01'	System	17 Aug 2020 00:01:53
	System	17 Aug 2020 00:01:53



**US3462091**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:58', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:01', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'No (N)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered '10 Aug 2020 11:53'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 11:03'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 13:33'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:23', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c' User entered 'None (0)'	System	11 Aug 2020 00:05:53
	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:32', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'No (N)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered '10 Aug 2020 17:05'	System	11 Aug 2020 00:05:53

**US3462091**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Aug 2020 14:28'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:13:44



**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 2'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'No (N)'	System	12 Aug 2020 01:09:55



**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered '11 Aug 2020 18:09'	System	12 Aug 2020 01:09:55

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 3'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:32', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679' User entered 'None (0)'	System	13 Aug 2020 01:03:55
	System	13 Aug 2020 01:03:55



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:42', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'No (N)'	System	13 Aug 2020 01:03:55

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:52', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered '12 Aug 2020 18:03'	System	13 Aug 2020 01:03:55

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 4'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:40', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:47', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'No (N)'	System	14 Aug 2020 00:03:55

**US3462091**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:52', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered '13 Aug 2020 17:03'	System	14 Aug 2020 00:03:55

**US3462091**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:13:44



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 5'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:40', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec' User entered 'None (0)'	System	15 Aug 2020 03:15:52
	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:42', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec' User entered 'None (0)'	System	15 Aug 2020 03:15:52
	System	15 Aug 2020 03:15:52



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'No (N)'	System	15 Aug 2020 03:15:52

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered '14 Aug 2020 20:15'	System	15 Aug 2020 03:15:52

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 6'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:53', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'No (N)'	System	16 Aug 2020 01:33:04

**US3462091**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered '15 Aug 2020 18:32'	System	16 Aug 2020 01:33:04

**US3462091**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 7'	System	10 Aug 2020 18:13:44



US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:57', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'No (N)'	System	17 Aug 2020 00:02:14

**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:13', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered '16 Aug 2020 17:02'	System	17 Aug 2020 00:02:14



**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:42

**US3462091**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:42

**US3462091**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:42

**US3462091**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:42

**US3462091**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:21:46

**US3462091**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'I'	System	08 Sep 2020 18:21:46



**US3462091**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:06

**US3462091**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:06

**US3462091**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:06

**US3462091**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:06

**US3462091**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:10

**US3462091**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:46:51
User entered 'I'	System	08 Sep 2020 18:22:10

**US3462091**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:21

**US3462091**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:21



**US3462091**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:21

**US3462091**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:21

**US3462091**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:22:50

**US3462091**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:57:08
User entered 'I'	System	08 Sep 2020 18:22:50

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:08

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:08

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[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 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:08

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'VISIT2'	System	08 Sep 2020 18:23:08



US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '08 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10:23'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered '08 Sep 2020 10:23'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '98.0' F	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Tympanic'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25



**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '69'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'bpm'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '16'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'breaths/min'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '121'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'mmHg'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '74'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'mmHg'	System	21 Sep 2020 18:57:25



US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '08 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '11:42'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered '08 Sep 2020 11:42'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '97.7' F	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Tympanic'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25



US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '63'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'bpm'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '12'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'breaths/min'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '117'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'mmHg'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '75'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'mmHg'	System	21 Sep 2020 18:57:25



**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:38:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:31

US3462091

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:31

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:29

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:29

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:29

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '11:05'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:29



**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered '8 Sep 2020 11:05'	System	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:38:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:23:29

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'ONCE'	System	08 Sep 2020 18:23:29

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:38:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:59

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '08 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:59

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '10:58'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:57:59

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered '08 Sep 2020 10:58'	System	21 Sep 2020 18:57:59



US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:38:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	21 Sep 2020 18:55:52
User entered '08 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:52
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).		
User entered '11 Sep 2020'	System	21 Sep 2020 18:55:27
	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:38:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '11:00'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered '08 Sep 2020 11:00'	System	21 Sep 2020 18:55:52
User entered '11 Sep 2020 11:00'	System	21 Sep 2020 18:55:27

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:38:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 19:02:48
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:02:48
User entered '11:00'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27



**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered empty.	System	09 Oct 2020 19:02:48
User entered '08 Sep 2020 11:00'	System	21 Sep 2020 18:55:52
User entered '11 Sep 2020 11:00'	System	21 Sep 2020 18:55:27

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	21 Sep 2020 18:58:13

**US3462091**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'I'	System	21 Sep 2020 18:58:13

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:39:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered 'Yes (Y)'	System	08 Sep 2020 18:40:25

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered '97.7'	System	08 Sep 2020 18:40:25

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered 'No (N)'	System	08 Sep 2020 18:40:25

**US3462091**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:23', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered '08 Sep 2020 11:40'	System	08 Sep 2020 18:40:25



US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 11:25'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 13:55'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567'	System	09 Sep 2020 01:42:40
User entered 'Yes (Y)'	System	09 Sep 2020 01:42:40

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567' User entered '98.0'	System	09 Sep 2020 01:42:40
	System	09 Sep 2020 01:42:40

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567'	System	09 Sep 2020 01:42:40
User entered 'No (N)'	System	09 Sep 2020 01:42:40

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567'	System	09 Sep 2020 01:42:40
User entered '08 Sep 2020 18:42'	System	09 Sep 2020 01:42:40

**US3462091**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 18:23:29



US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 2'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:56:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6'	System	10 Sep 2020 00:57:15
User entered 'Yes (Y)'	System	10 Sep 2020 00:57:15

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:56:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6' User entered '98.7'	System	10 Sep 2020 00:57:15
	System	10 Sep 2020 00:57:15

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6'	System	10 Sep 2020 00:57:15
User entered 'No (N)'	System	10 Sep 2020 00:57:15

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6'	System	10 Sep 2020 00:57:15
User entered '09 Sep 2020 17:57'	System	10 Sep 2020 00:57:15

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:23:29



US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 3'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466'	System	11 Sep 2020 00:33:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:33:23

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466' User entered '97.6'	System	11 Sep 2020 00:33:23
	System	11 Sep 2020 00:33:23

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:17', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466'	System	11 Sep 2020 00:33:23
User entered 'No (N)'	System	11 Sep 2020 00:33:23

**US3462091**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466' User entered '10 Sep 2020 17:33'	System	11 Sep 2020 00:33:23
	System	11 Sep 2020 00:33:23

**US3462091**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 4'	System	08 Sep 2020 18:23:29



US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:50:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29'	System	12 Sep 2020 01:51:07
User entered 'Yes (Y)'	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:50:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29' User entered '98.2'	System	12 Sep 2020 01:51:07
	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29'	System	12 Sep 2020 01:51:07
User entered 'No (N)'	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29'	System	12 Sep 2020 01:51:07
User entered '11 Sep 2020 18:51'	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 5'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c'	System	13 Sep 2020 03:35:36
User entered 'Yes (Y)'	System	13 Sep 2020 03:35:36



US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c' User entered '97.0'	System	13 Sep 2020 03:35:36
	System	13 Sep 2020 03:35:36

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:30', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c'	System	13 Sep 2020 03:35:36
User entered 'No (N)'	System	13 Sep 2020 03:35:36

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c'	System	13 Sep 2020 03:35:36
User entered '12 Sep 2020 20:35'	System	13 Sep 2020 03:35:36

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 6'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:44:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9' User entered 'Yes (Y)'	System	14 Sep 2020 02:45:07
	System	14 Sep 2020 02:45:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:44:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9' User entered '97.5'	System	14 Sep 2020 02:45:07
	System	14 Sep 2020 02:45:07



US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9'	System	14 Sep 2020 02:45:07
User entered 'No (N)'	System	14 Sep 2020 02:45:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9'	System	14 Sep 2020 02:45:07
User entered '13 Sep 2020 19:45'	System	14 Sep 2020 02:45:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 7'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:47:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe' User entered 'Yes (Y)'	System	15 Sep 2020 00:48:27
	System	15 Sep 2020 00:48:27

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe' User entered '97.0'	System	15 Sep 2020 00:48:27
	System	15 Sep 2020 00:48:27

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe'	System	15 Sep 2020 00:48:27
User entered 'No (N)'	System	15 Sep 2020 00:48:27



**US3462091**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe' User entered '14 Sep 2020 17:48'	System	15 Sep 2020 00:48:27
	System	15 Sep 2020 00:48:27

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered 'None (1)'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered 'No (N)'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered 'No (N)'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43' User entered 'None (1)'	System	08 Sep 2020 18:40:57
	System	08 Sep 2020 18:40:57



**US3462091**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered '08 Sep 2020 11:40'	System	08 Sep 2020 18:40:57

**US3462091**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 11:25'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 13:55'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b' User entered 'None (1)'	System	09 Sep 2020 01:43:09
	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b' User entered 'No (N)'	System	09 Sep 2020 01:43:09
	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b' User entered 'No (N)'	System	09 Sep 2020 01:43:09
	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:01', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b' User entered 'None (1)'	System	09 Sep 2020 01:43:09
	System	09 Sep 2020 01:43:09



**US3462091**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b' User entered '08 Sep 2020 18:43'	System	09 Sep 2020 01:43:09
	System	09 Sep 2020 01:43:09

**US3462091**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 2'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered 'No (N)'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered 'No (N)'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999' User entered 'None (1)'	System	10 Sep 2020 00:57:48
	System	10 Sep 2020 00:57:48



**US3462091**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered '09 Sep 2020 17:57'	System	10 Sep 2020 00:57:48

**US3462091**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 3'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'None (1)'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'No (N)'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'No (N)'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'None (1)'	System	11 Sep 2020 00:33:48



**US3462091**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered '10 Sep 2020 17:33'	System	11 Sep 2020 00:33:48

**US3462091**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 4'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba' User entered 'None (1)'	System	12 Sep 2020 01:51:25
	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba' User entered 'No (N)'	System	12 Sep 2020 01:51:25
	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba' User entered 'No (N)'	System	12 Sep 2020 01:51:25
	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba' User entered 'None (1)'	System	12 Sep 2020 01:51:25
	System	12 Sep 2020 01:51:25



**US3462091**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba' User entered '11 Sep 2020 18:51'	System	12 Sep 2020 01:51:25
	System	12 Sep 2020 01:51:25

**US3462091**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 5'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:40', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857' User entered 'None (1)'	System	13 Sep 2020 03:35:58
	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered 'No (N)'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:47', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered 'No (N)'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857' User entered 'None (1)'	System	13 Sep 2020 03:35:58
	System	13 Sep 2020 03:35:58



**US3462091**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered '12 Sep 2020 20:35'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 6'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:09', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered 'None (1)'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered 'No (N)'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered 'No (N)'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909' User entered 'None (1)'	System	14 Sep 2020 02:45:28
	System	14 Sep 2020 02:45:28



**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered '13 Sep 2020 19:45'	System	14 Sep 2020 02:45:28

**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 7'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered 'None (1)'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered 'No (N)'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered 'No (N)'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225' User entered 'None (1)'	System	15 Sep 2020 00:48:45
	System	15 Sep 2020 00:48:45



US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered '14 Sep 2020 17:48'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:38:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5' User entered 'None (0)'	System	08 Sep 2020 18:41:29
	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5' User entered 'None (0)'	System	08 Sep 2020 18:41:29
	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:09', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5' User entered 'None (0)'	System	08 Sep 2020 18:41:29
	System	08 Sep 2020 18:41:29



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'No (N)'	System	08 Sep 2020 18:41:29

**US3462091**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:24', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered '08 Sep 2020 11:41'	System	08 Sep 2020 18:41:29

**US3462091**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 11:25'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 13:55'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:32', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'No (N)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

**US3462091**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered '08 Sep 2020 18:43'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

**US3462091**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 18:23:29



**US3462091**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 2'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7' User entered 'None (0)'	System	10 Sep 2020 00:58:34
	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'No (N)'	System	10 Sep 2020 00:58:34

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered '09 Sep 2020 17:58'	System	10 Sep 2020 00:58:34

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 3'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:53', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:34:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:34:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'No (N)'	System	11 Sep 2020 00:34:13

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:34:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered '10 Sep 2020 17:34'	System	11 Sep 2020 00:34:13

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 4'	System	08 Sep 2020 18:23:29



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc' User entered 'None (0)'	System	12 Sep 2020 01:51:48
	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc' User entered 'None (0)'	System	12 Sep 2020 01:51:48
	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc' User entered 'None (0)'	System	12 Sep 2020 01:51:48
	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'No (N)'	System	12 Sep 2020 01:51:48

**US3462091**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered '11 Sep 2020 18:51'	System	12 Sep 2020 01:51:48



**US3462091**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 5'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:58', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'None (0)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:01', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'None (0)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'None (0)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'None (0)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'None (0)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21



**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'None (0)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'No (N)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered '12 Sep 2020 20:36'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

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

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 6'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53



US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e'	System	14 Sep 2020 02:45:53
User entered 'No (N)'	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:38:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e'	System	14 Sep 2020 02:45:53
User entered '13 Sep 2020 19:45'	System	14 Sep 2020 02:45:53

**US3462091**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:23:29



**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 7'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered 'None (0)'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:57', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered 'None (0)'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered 'None (0)'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered 'None (0)'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered 'None (0)'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered 'None (0)'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:13', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered 'No (N)'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19



**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf' User entered '14 Sep 2020 17:49'	System	15 Sep 2020 00:49:19
	System	15 Sep 2020 00:49:19

**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

**US3462091**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:38:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

**US3462091**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:05

**US3462091**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:05

**US3462091**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:05

**US3462091**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:05

**US3462091**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:09



**US3462091**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User entered 'I'	System	08 Oct 2020 22:47:09

**US3462091**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:21

**US3462091**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:21

**US3462091**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:21

**US3462091**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:21

**US3462091**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:24

**US3462091**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User entered 'I'	System	08 Oct 2020 22:47:24

**US3462091**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:38



**US3462091**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:38

**US3462091**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:38

**US3462091**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:38

**US3462091**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:41

**US3462091**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User entered 'I'	System	08 Oct 2020 22:47:41

US3462091

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Per GCL there is a Swab sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'Updated Missing Data' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM). User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 11:29:32 09 Feb 2021 18:00:22 08 Feb 2021 22:48:37 08 Oct 2020 22:47:52

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:52

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[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 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 22:47:52



**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'VISIT3'	System	08 Oct 2020 22:47:52

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered empty.	System	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08



**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered empty.	System	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered empty.	System	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered empty.	System	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:08

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered empty.	System	08 Oct 2020 23:05:08



**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:38:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:14

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:38:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:14

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:45

US3462091

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12Jan2021 is reported under OL-1 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 appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:38:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12Jan2021 is reported under OL-1 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 appropriate visit. Else clarify, thank you.' answered with 'Updated Missing Data' (Site from DM).		09 Feb 2021 18:01:11
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12Jan2021 is reported under OL-1 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 appropriate visit. Else clarify, thank you.' (Site from DM).		08 Feb 2021 18:29:28
User entered '5 Oct 2020'		08 Oct 2020 23:05:45

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered '07:31'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:45

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered '5 Oct 2020 07:31'	System	08 Oct 2020 23:05:45



**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:22:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 23:05:20

**US3462091**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:46
User entered 'I'	System	08 Oct 2020 23:05:20

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 64'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:39:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'Yes (Y)'	System	15 Oct 2020 02:42:10

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:38:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:39:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'No (N)'	System	15 Oct 2020 02:42:10

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:39:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'No (N)'	System	15 Oct 2020 02:42:10

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:41:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'Yes (Y)'	System	15 Oct 2020 02:42:10

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:41:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Oct 2020 02:42:10



**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:41:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8' User entered '14 Oct 2020 19:41:59'	System	15 Oct 2020 02:42:10
	System	15 Oct 2020 02:42:10

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 71'	System	10 Aug 2020 18:13:44

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-19T19:03:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '5331bc50-d278-44a3-9abb-c72a7d635008'	System	20 Oct 2020 02:03:40
User entered 'No (N)'	System	20 Oct 2020 02:03:40

**US3462091**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-19T19:03:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '5331bc50-d278-44a3-9abb-c72a7d635008'	System	20 Oct 2020 02:03:40
User entered 'No (N)'	System	20 Oct 2020 02:03:40

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-19T19:03:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '5331bc50-d278-44a3-9abb-c72a7d635008' User entered '19 Oct 2020 19:03:38'	System	20 Oct 2020 02:03:40
	System	20 Oct 2020 02:03:40

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 18:13:44



**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 78'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-26T16:43:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acf8cc52-cfa1-4470-862d-adc64ab82977'	System	26 Oct 2020 23:44:21
User entered 'No (N)'	System	26 Oct 2020 23:44:21

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-26T16:44:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acf8cc52-cfa1-4470-862d-adc64ab82977'	System	26 Oct 2020 23:44:21
User entered 'No (N)'	System	26 Oct 2020 23:44:21

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-26T16:44:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acf8cc52-cfa1-4470-862d-adc64ab82977'	System	26 Oct 2020 23:44:21
User entered '26 Oct 2020 16:44:16'	System	26 Oct 2020 23:44:21

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 92'	System	10 Aug 2020 18:13:44



**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-09T22:23:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8828587c-9fa3-46eb-b6c5-60bf55bd7f51' User entered 'No (N)'	System	10 Nov 2020 06:23:21
	System	10 Nov 2020 06:23:21

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-09T22:23:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8828587c-9fa3-46eb-b6c5-60bf55bd7f51'	System	10 Nov 2020 06:23:21
User entered 'No (N)'	System	10 Nov 2020 06:23:21

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-09T22:23:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8828587c-9fa3-46eb-b6c5-60bf55bd7f51' User entered '09 Nov 2020 22:23:18'	System	10 Nov 2020 06:23:21
	System	10 Nov 2020 06:23:21

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 99'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-16T23:07:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '594a50d3-ad92-475c-bddf-7c80da097e45'	System	17 Nov 2020 07:07:40
User entered 'No (N)'	System	17 Nov 2020 07:07:40

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-16T23:07:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '594a50d3-ad92-475c-bddf-7c80da097e45'	System	17 Nov 2020 07:07:40
User entered 'No (N)'	System	17 Nov 2020 07:07:40



**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-16T23:07:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '594a50d3-ad92-475c-bddf-7c80da097e45'	System	17 Nov 2020 07:07:40
User entered '16 Nov 2020 23:07:38'	System	17 Nov 2020 07:07:40

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:13:17
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 18:13:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-25T07:58:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05fcbac6-040b-40e2-828f-cf383d28930d' User entered 'No (N)'	System	25 Nov 2020 15:58:31
	System	25 Nov 2020 15:58:31



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-25T07:58:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05fcbac6-040b-40e2-828f-cf383d28930d' User entered 'No (N)'	System	25 Nov 2020 15:58:31

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-25T07:58:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05fcbac6-040b-40e2-828f-cf383d28930d' User entered '25 Nov 2020 07:58:28'	System	25 Nov 2020 15:58:31
	System	25 Nov 2020 15:58:31

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-02T16:20:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b770568e-7746-42cc-934f-c97e72958e55' User entered 'No (N)'	System	03 Dec 2020 00:21:02
	System	03 Dec 2020 00:21:02

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-02T16:20:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b770568e-7746-42cc-934f-c97e72958e55'	System	03 Dec 2020 00:21:02
User entered 'No (N)'	System	03 Dec 2020 00:21:02

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-02T16:20:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b770568e-7746-42cc-934f-c97e72958e55'	System	03 Dec 2020 00:21:02
User entered '02 Dec 2020 16:20:59'	System	03 Dec 2020 00:21:02



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-09T12:46:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9af6d8e2-173f-4c2a-a625-c6b540ba67d8'	System	09 Dec 2020 20:46:28
User entered 'No (N)'	System	09 Dec 2020 20:46:28

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-09T12:46:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9af6d8e2-173f-4c2a-a625-c6b540ba67d8'	System	09 Dec 2020 20:46:28
User entered 'No (N)'	System	09 Dec 2020 20:46:28

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-09T12:46:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9af6d8e2-173f-4c2a-a625-c6b540ba67d8' User entered '09 Dec 2020 12:46:25'	System	09 Dec 2020 20:46:28
	System	09 Dec 2020 20:46:28

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-16T13:53:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'efdfd2dc-bacc-44d3-8fa4-1137f099c238'	System	18 Mar 2021 20:20:42
User entered 'No (N)'	System	18 Mar 2021 20:20:42

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-16T13:53:23', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'efdfd2dc-bacc-44d3-8fa4-1137f099c238'	System	18 Mar 2021 20:20:42
User entered 'No (N)'	System	18 Mar 2021 20:20:42

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-16T13:53:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'efdfd2dc-bacc-44d3-8fa4-1137f099c238' User entered '16 Dec 2020 13:53:27'	System	18 Mar 2021 20:20:42

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-23T08:12:01', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acdae817-7b56-4bff-b392-3e18f75916d8'	System	18 Mar 2021 20:20:59
User entered 'No (N)'	System	18 Mar 2021 20:20:59



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-23T08:12:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acdae817-7b56-4bff-b392-3e18f75916d8'	System	18 Mar 2021 20:20:59
User entered 'No (N)'	System	18 Mar 2021 20:20:59

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-23T08:12:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acdae817-7b56-4bff-b392-3e18f75916d8' User entered '23 Dec 2020 08:12:06'	System	18 Mar 2021 20:20:59
	System	18 Mar 2021 20:20:59

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-30T06:45:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9772b30f-48b5-47c0-980b-fb0cd93852c1' User entered 'No (N)'	System	18 Mar 2021 20:20:44
	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-30T06:45:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9772b30f-48b5-47c0-980b-fb0cd93852c1' User entered 'No (N)'	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-12-30T06:45:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9772b30f-48b5-47c0-980b-fb0cd93852c1' User entered '30 Dec 2020 06:45:18'	System	18 Mar 2021 20:20:44



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-06T06:32:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '51488cc8-308b-4a59-983f-fad0a48a1bd0'	System	18 Mar 2021 20:20:59
User entered 'No (N)'	System	18 Mar 2021 20:20:59

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-06T06:32:23', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '51488cc8-308b-4a59-983f-fad0a48a1bd0'	System	18 Mar 2021 20:20:59
User entered 'No (N)'	System	18 Mar 2021 20:20:59

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-06T06:32:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '51488cc8-308b-4a59-983f-fad0a48a1bd0' User entered '06 Jan 2021 06:32:27'	System	18 Mar 2021 20:20:59
	System	18 Mar 2021 20:20:59

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-13T08:57:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4edb988-223f-460a-9130-7e0049e93bbf'	System	18 Mar 2021 20:20:44
User entered 'No (N)'	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-13T08:57:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4edb988-223f-460a-9130-7e0049e93bbf'	System	18 Mar 2021 20:20:44
User entered 'No (N)'	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-13T08:57:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4edb988-223f-460a-9130-7e0049e93bbf' User entered '13 Jan 2021 08:57:56'	System	18 Mar 2021 20:20:44
	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-20T18:40:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '74dbdd6a-93c5-488d-bd34-0ef6f62c0946'	System	18 Mar 2021 20:20:44
User entered 'No (N)'	System	18 Mar 2021 20:20:44



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-20T18:41:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '74dbdd6a-93c5-488d-bd34-0ef6f62c0946'	System	18 Mar 2021 20:20:44
User entered 'No (N)'	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-20T18:41:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '74dbdd6a-93c5-488d-bd34-0ef6f62c0946' User entered '20 Jan 2021 18:41:10'	System	18 Mar 2021 20:20:44
	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-27T17:06:58', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'aff21e50-45c3-4bdb-8316-972e928af11e' User entered 'No (N)'	System	18 Mar 2021 20:21:00
	System	18 Mar 2021 20:21:00

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-27T17:07:09', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'aff21e50-45c3-4bdb-8316-972e928af11e'	System	18 Mar 2021 20:21:00
User entered 'No (N)'	System	18 Mar 2021 20:21:00

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-01-27T17:07:13', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'aff21e50-45c3-4bdb-8316-972e928af11e' User entered '27 Jan 2021 17:07:13'	System	18 Mar 2021 20:21:00
	System	18 Mar 2021 20:21:00



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-03T20:37:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'bde921ca-d1df-4358-b549-0dddf3012bbc' User entered 'No (N)'	System	18 Mar 2021 20:20:44
	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-03T20:38:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'bde921ca-d1df-4358-b549-0dddf3012bbc'	System	18 Mar 2021 20:20:44
User entered 'No (N)'	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-03T20:38:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'bde921ca-d1df-4358-b549-0dddf3012bbc' User entered '03 Feb 2021 20:38:04'	System	18 Mar 2021 20:20:44
	System	18 Mar 2021 20:20:44

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-10T17:04:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '47e4e6ca-8db2-4037-bd3d-427491a0bfa8'	System	18 Mar 2021 20:20:46
User entered 'No (N)'	System	18 Mar 2021 20:20:46

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-10T17:04:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '47e4e6ca-8db2-4037-bd3d-427491a0bfa8'	System	18 Mar 2021 20:20:46
User entered 'No (N)'	System	18 Mar 2021 20:20:46

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-10T17:04:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '47e4e6ca-8db2-4037-bd3d-427491a0bfa8' User entered '10 Feb 2021 17:04:37'	System	18 Mar 2021 20:20:46
	System	18 Mar 2021 20:20:46

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-18T18:10:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2e1021bf-8d43-4258-b4b5-1abd30ce773c'	System	18 Mar 2021 20:20:47
User entered 'No (N)'	System	18 Mar 2021 20:20:47



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-18T18:10:40', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2e1021bf-8d43-4258-b4b5-1abd30ce773c'	System	18 Mar 2021 20:20:47
User entered 'No (N)'	System	18 Mar 2021 20:20:47

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-18T18:10:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2e1021bf-8d43-4258-b4b5-1abd30ce773c' User entered '18 Feb 2021 18:10:43'	System	18 Mar 2021 20:20:47
	System	18 Mar 2021 20:20:47

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-24T08:59:57', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0fe876d0-2015-4990-a2dc-1d3ce39ed176'	System	18 Mar 2021 20:20:47
User entered 'No (N)'	System	18 Mar 2021 20:20:47

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-24T09:00:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0fe876d0-2015-4990-a2dc-1d3ce39ed176'	System	18 Mar 2021 20:20:47
User entered 'No (N)'	System	18 Mar 2021 20:20:47

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-02-24T09:00:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0fe876d0-2015-4990-a2dc-1d3ce39ed176' User entered '24 Feb 2021 09:00:04'	System	18 Mar 2021 20:20:47
	System	18 Mar 2021 20:20:47



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-03T19:16:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '82a8d4ca-a15b-4f10-93c6-82c96c680d46'	System	18 Mar 2021 20:20:47
User entered 'No (N)'	System	18 Mar 2021 20:20:47

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-03T19:17:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '82a8d4ca-a15b-4f10-93c6-82c96c680d46'	System	18 Mar 2021 20:20:47
User entered 'No (N)'	System	18 Mar 2021 20:20:47

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-03T19:17:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '82a8d4ca-a15b-4f10-93c6-82c96c680d46' User entered '03 Mar 2021 19:17:10'	System	18 Mar 2021 20:20:47
	System	18 Mar 2021 20:20:47

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:06:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e'	System	18 Mar 2021 20:20:57
User entered 'Yes (Y)'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:09:58', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered 'Yes (Y)'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:07:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e'	System	18 Mar 2021 20:20:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:07:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered 'Yes (Y)'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '1'	System	18 Mar 2021 20:20:57



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '1'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '1'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e'	System	18 Mar 2021 20:20:57
User entered '1'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '1'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '0'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:08:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '1'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:09:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e'	System	18 Mar 2021 20:20:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:09:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e'	System	18 Mar 2021 20:20:57
User entered 'Yes (Y)'	System	18 Mar 2021 20:20:57



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Please 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:09:42', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e'	System	18 Mar 2021 20:20:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-10T14:10:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4144fa62-a2e1-4cec-93cf-5e7a2240b30e' User entered '10 Mar 2021 14:10:02'	System	18 Mar 2021 20:20:57
	System	18 Mar 2021 20:20:57

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-17T08:42:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'ec967979-e9f2-4f57-baff-6f9cf5010d52'	System	18 Mar 2021 20:20:49
User entered 'No (N)'	System	18 Mar 2021 20:20:49

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-17T08:42:47', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'ec967979-e9f2-4f57-baff-6f9cf5010d52'	System	18 Mar 2021 20:20:49
User entered 'No (N)'	System	18 Mar 2021 20:20:49

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-17T08:42:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'ec967979-e9f2-4f57-baff-6f9cf5010d52'	System	18 Mar 2021 20:20:49
User entered '17 Mar 2021 08:42:50'	System	18 Mar 2021 20:20:49



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:13:55



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:13:55



**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:13:55

**US3462091**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:38:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:13:55



US3462091

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:38:10**

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)	26 Apr 2021 06:39:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-18T13:24:53-07:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '447bbd03-e966-4ab3-9937-f651e82edbf4'	System	18 Mar 2021 20:24:59
User entered 'No (N)'	System	18 Mar 2021 20:24:59

**US3462091**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:39:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2021-03-18T13:24:56-07:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '447bbd03-e966-4ab3-9937-f651e82edbf4' User entered '18 Mar 2021 13:24:56'	System	18 Mar 2021 20:24:59
	System	18 Mar 2021 20:24:59

**US3462091**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:51:54

**US3462091**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:51:54

**US3462091**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:51:54

**US3462091**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:51:54

**US3462091**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:02:02

**US3462091**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:55:44
User entered 'I'	System	15 Mar 2021 19:02:02



**US3462091**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:52:23

**US3462091**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:52:23

**US3462091**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:52:23

**US3462091**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:52:23

**US3462091**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 19:02:10

**US3462091**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User entered 'I'	System	15 Mar 2021 19:02:10

**US3462091**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:52:38

**US3462091**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered '05 Jan 2021'	(b) (4), (b) (6)	30 Mar 2021 17:52:38



**US3462091**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:52:38

**US3462091**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:52:38

**US3462091**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 19:02:20

**US3462091**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:22:34
User entered 'I'	System	15 Mar 2021 19:02:20

**US3462091**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:27:51

**US3462091**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:27:51

**US3462091**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:27:51

**US3462091**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:38:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:27:51



**US3462091**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:02:28

**US3462091**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User entered 'I'	System	15 Mar 2021 19:02:28

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:02:44

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:02:44

US3462091

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:02:44

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered 'VISIT4'	System	15 Mar 2021 19:02:44

US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:30:32

US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:30:32



**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '10:16'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:30:32

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered '15 Mar 2021 10:16'	System	31 Mar 2021 17:30:32

US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '98' F	(b) (4), (b) (6)	31 Mar 2021 17:30:32

US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:30:32

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:30:32

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '67'	(b) (4), (b) (6)	31 Mar 2021 17:30:32

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered 'bpm'	System	31 Mar 2021 17:30:32

US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '17'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:30:32



US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered 'breaths/min'	System	31 Mar 2021 17:30:32

US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '121'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:30:32

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered 'mmHg'	System	31 Mar 2021 17:30:32

US3462091

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:38:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 17:36:00
User entered '81'	(b) (4), (b) (6)	31 Mar 2021 17:30:32

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered 'mmHg'	System	31 Mar 2021 17:30:32

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:38:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30

US3462091

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:02:58



US3462091

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:38:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:02:58

US3462091

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:38:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:03:19

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:03:19

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '10:40'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:03:19

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered '15 Mar 2021 10:40'	System	15 Mar 2021 19:03:19

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:03:26

**US3462091**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:30
User entered '1'	System	15 Mar 2021 19:03:26

US3462091

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:30:18
User entered 'Yes (Y)' reason for change: Data Entry Error		09 Feb 2021 18:06:06
Query 'Data is required. Please complete.' answered with 'subject decided to continue study blinded' (Site from System).		09 Feb 2021 18:05:22
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 18:04:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:04:38
User entered 'Yes (Y)'		09 Feb 2021 18:01:53



US3462091

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:38:10

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:06
User entered empty; reason for change Data Entry Error		09 Feb 2021 18:04:38
User entered '12 Jan 2021'		09 Feb 2021 18:01:53

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:01:53

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:38:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 18:06:06
User entered empty.	System	09 Feb 2021 18:04:38
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 18:01:53

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:26
User entered empty; reason for change Data Entry Error		09 Feb 2021 18:04:13
User entered '17 Dec 2020'		09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:36:06

US3462091

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:38:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:29:06
User entered 'No (N)' reason for change: Data Entry Error		09 Feb 2021 18:06:26
Query 'Data is required. Please complete.' answered with 'Subject decided to continue study blinded ' (Site from System).		09 Feb 2021 18:05:04
User closed query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	System	09 Feb 2021 18:04:13
Query 'Was the participant unblinded is No however, System data is present. Please reconcile.' answered by data change (Site from System).		09 Feb 2021 18:04:13
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 18:04:13
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:04:13
User opened query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	System	09 Feb 2021 18:03:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty. WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:36:06

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:04:24
User entered '12 Jan 2021'		09 Feb 2021 18:03:54



**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User entered empty.	System	09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:38:10**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User entered empty.	System	09 Feb 2021 18:03:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:43

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:43



**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '09:34'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:43

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User entered '12 Jan 2021 09:34'	System	09 Feb 2021 18:06:43

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:38:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '09:22'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:06:54

**US3462091**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:38:10**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:02:28
User entered '12 Jan 2021 09:22'	System	09 Feb 2021 18:06:54

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:38:10**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:19
User entered 'Yes (Y)'		19 Oct 2020 21:50:25

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
Reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 06:33:27
DataPoint Verified.		06 Nov 2020 19:15:48
Reviewed for Safety.		20 Oct 2020 16:46:44
User entered 'USA-US093-2020-mRNA-1273-P301000007'	System	20 Oct 2020 16:46:40
User entered 'New'	(b) (4), (b) (6)	20 Oct 2020 16:46:40



US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luckinger (b) (4)	19 Mar 2021 19:06:18
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so.' (Site from Safety).	(b) (4)	09 Nov 2020 11:04:21
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so.' answered with 'PATIENT REPORTS NO KNOWN CAUSE AND IS UNCLEAR ON DETAILS. WAITING FOPR MEDICAL RECORDS.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:01:34
DataPoint Verified.		06 Nov 2020 19:15:48
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so.' (Site from Safety).		30 Oct 2020 00:20:18
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: Neck pain, LLT: Neck pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:01:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:01:22
Data point term sent to Coder	System	19 Oct 2020 22:00:19
User entered 'neck pain'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Yes (Y)'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'No (N)'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'No (N)'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '09 Oct 2020'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:58:40
DataPoint Un-verified.		07 Nov 2020 20:00:37
User entered 'No (N)' reason for change: Data Entry Error		07 Nov 2020 20:00:37
DataPoint Verified.		06 Nov 2020 19:15:48
User entered 'Yes (Y)'		19 Oct 2020 21:59:37



US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:34:26
Signature has been broken.		07 Apr 2021 18:34:26
User entered '29 Dec 2020' reason for change: Per Query Resolution		07 Apr 2021 18:34:26
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:58:41
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		09 Nov 2020 11:04:25
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ADDED' (Site from Safety).		07 Nov 2020 20:01:05
DataPoint Un-verified.		07 Nov 2020 20:00:37
User entered '14 Oct 2020' reason for change: Data Entry Error		07 Nov 2020 20:00:37
DataPoint Verified.		06 Nov 2020 19:15:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		30 Oct 2020 00:16:23
User entered empty.		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Grade 4 (Grade 4)'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Yes (Y)'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'I'		19 Oct 2020 21:59:37



**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '09 Oct 2020'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '14 Oct 2020'		19 Oct 2020 21:59:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:06:18
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	04 Feb 2021 17:37:05
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		04 Feb 2021 17:37:05
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 17:37:05
User entered 'No (N)' reason for change: Data Entry Error		04 Feb 2021 17:37:05
DataPoint Verified.		06 Nov 2020 19:15:48
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Oct 2020 21:59:37
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'		19 Oct 2020 21:59:37

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'		19 Oct 2020 21:59:37

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'		19 Oct 2020 21:59:37

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Not Related (NOT RELATED)'		19 Oct 2020 21:59:37



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Not Related (NOT RELATED)'		19 Oct 2020 21:59:37

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Not Applicable (NOT APPLICABLE)'		19 Oct 2020 21:59:37

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:40:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'		19 Oct 2020 21:59:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'ADDED' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:47:26  07 Nov 2020 20:01:47  06 Nov 2020 19:15:48
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM). User entered 'I'		29 Oct 2020 00:03:39  19 Oct 2020 21:59:37



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:10

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (d) (4), (b) (6)	09 Nov 2020 11:04:32
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED' (Site from Safety).		07 Nov 2020 20:03:43
DataPoint Un-verified.		07 Nov 2020 20:00:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:		07 Nov 2020 20:00:37
Data Entry Error		
DataPoint Verified.		06 Nov 2020 19:15:48
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		30 Oct 2020 00:16:50
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		19 Oct 2020 21:59:37

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.		19 Oct 2020 21:59:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:10

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User closed query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' (Site from Safety).	(b) (4) (d) (4), (b) (6)	05 Feb 2021 13:58:43
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).		05 Feb 2021 13:58:39
User closed query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).		05 Feb 2021 13:58:34
User closed query 'PV Query: Please provide results of spinal tap.' (Site from Safety).		05 Feb 2021 13:58:30
User closed query 'PV Query: The subject was treated with antibiotics. Please provide the indication ' (Site from Safety).		05 Feb 2021 13:58:25
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so. ' (Site from Safety).		05 Feb 2021 13:58:15
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so. ' answered with 'Due to not having medical Records we can not determine this ' (Site from Safety).		04 Feb 2021 18:18:00
Query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' answered with 'Negative' (Site from Safety).		04 Feb 2021 18:17:27
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 'Requested Medical Records 3 Times and they have not been sent to us ' (Site from Safety).		04 Feb 2021 18:17:11



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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' answered with 'Culter' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 17:44:32
Query 'PV Query: Please provide results of spinal tap.' answered with 'Negative' (Site from Safety).		04 Feb 2021 17:42:06
Query 'PV Query: The subject was treated with antibiotics. Please provide the indication. ' answered with 'indication was for severe back and neck pain' (Site from Safety).		04 Feb 2021 17:41:58
User opened query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' (Site from Safety).		11 Jan 2021 17:27:31
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).		11 Jan 2021 17:27:21
User opened query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).		11 Jan 2021 17:27:09
User opened query 'PV Query: Please provide results of spinal tap.' (Site from Safety).		11 Jan 2021 17:26:53
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).		08 Jan 2021 16:37:09
User closed query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).		08 Jan 2021 16:37:06
User closed query 'PV Query: Please provide results of spinal tap. ' (Site from Safety).		08 Jan 2021 16:35:50
User closed query 'PV Query: Please provide diagnostic test results (i.e, spinal CT/MRI, etc) performed in evaluation of the event. ' (Site from Safety).		08 Jan 2021 16:35:46

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:10

[Narrative](#)

Audit	User	Time (GMT)
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 'Still waiting for medical records to be sent. Initial request sent at the end of OCT2020. Request sent again today.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 18:27:27
Query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' answered with 'Still waiting for medical records to be sent. Initial request sent at the end of OCT2020. Request sent again today.' (Site from Safety).		07 Jan 2021 18:27:14
Query 'PV Query: Please provide results of spinal tap. ' answered with 'Still waiting for medical records to be sent. Initial request sent at the end of OCT2020. Request sent again today.' (Site from Safety).		07 Jan 2021 18:27:09
Query 'PV Query: Please provide diagnostic test results (i.e, spinal CT/MRI, etc) performed in evaluation of the event. ' answered with 'Still waiting for medical records to be sent. Initial request sent at the end of OCT2020. Request sent again today.' (Site from Safety).		07 Jan 2021 18:27:05
User opened query 'PV Query: The subject was treated with antibiotics. Please provide the indication. ' (Site from Safety).		17 Nov 2020 21:51:16
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).		17 Nov 2020 21:51:02
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so. ' (Site from Safety).		17 Nov 2020 21:50:44
User opened query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).		17 Nov 2020 21:50:20
User opened query 'PV Query: Please provide results of spinal tap. ' (Site from Safety).		17 Nov 2020 21:50:03

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide diagnostic test results (i.e, spinal CT/MRI, etc) performed in evaluation of the event. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:48
		17 Nov 2020 19:59:03
User closed query 'Per DM CLR: SAE narrative indicates OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS were given. However, there are no corresponding ConMed record to match these information. Please update to record these medications as appropriate. Otherwise, clarify.' (Site from DM).		13 Nov 2020 14:48:06
User closed query 'Per DM CLR: SAE Narrative indicates that the subject underwent 3 Spinal taps and an E. Coli test. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).		13 Nov 2020 14:48:01
User closed query 'PV Query: The subject was treated with antibiotics. Please provide the indication.' (Site from Safety).		09 Nov 2020 11:04:57
User closed query 'PV Query: Please provide results of spinal tap.' (Site from Safety).		09 Nov 2020 11:04:55
User closed query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).		09 Nov 2020 11:04:52
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).		09 Nov 2020 11:04:49
User closed query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' (Site from Safety).		09 Nov 2020 11:04:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:38:10

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm the treatment dates in the narrative, as the event occurred in October, but treatment dates are reported as in September.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:39
Query 'PV Query: The subject was treated with antibiotics. Please provide the indication.' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).		07 Nov 2020 20:06:09
Query 'PV Query: Please provide results of spinal tap.' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).		07 Nov 2020 20:06:04
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 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. RECORDS REQUESTED 10/19 AND AGAIN 10/30/20.' (Site from Safety).		07 Nov 2020 20:06:00
Query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).		07 Nov 2020 20:05:24
Query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).		07 Nov 2020 20:04:31
Query 'PV Query: Please confirm the treatment dates in the narrative, as the event occurred in October, but treatment dates are reported as in September.' answered with 'CORRECTED' (Site from Safety).		07 Nov 2020 20:04:15

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE narrative indicates OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS were given. However, there are no corresponding ConMed record to match these information. Please update to record these medications as appropriate. Otherwise, clarify.'	(b) (4), (b) (6)	07 Nov 2020 20:04:07
answered with 'ADDED' (Site from DM). Query 'Per DM CLR: SAE Narrative indicates that the subject underwent 3 Spinal taps and an E. Coli test. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.'		07 Nov 2020 20:04:02
answered with 'ADDED' (Site from DM). DataPoint Un-verified.		07 Nov 2020 20:00:37
User entered 'PER PATIENT REPORT OVER PHONE ON 19OCT20 AT 13:22, ON 09OCT20 PATIENT HAD SYMPTOMS OF SEVERE NECK/BACK PAIN STARTING WITH NO KNOWN TRIGGER/INCIDENT. WIFE DROVE PATIENT TO ER AND PATIENT WAS HOSPITALIZED FOR 5 NIGHTS. PER PATIENT, 3 SPINAL TAPS WERE DONE, AND AN ECOLI AND COVID TEST PERFORMED, AND ALL FINDINGS WERE NEGATIVE. PER PATIENT, OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS. PATIENT WAS ON IV FLUIDS 10/9-10/14. PATIENT DOES RECALL ALL MEDICATION DETAILS. PATIENT FEELS MUCH IMPROVED AND LAST DOSE OF ANTIBIOTICS AND PAIN MEDICATION WAS 10/16/2020. MEDICAL RECORDS WILL BE REQUESTED FOR MORE DETAILS.'		07 Nov 2020 20:00:37
reason for change: Data Entry Error DataPoint Verified.		06 Nov 2020 19:15:48

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The subject was treated with antibiotics. Please provide the indication.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 00:20:56
User opened query 'PV Query: Please provide results of spinal tap.' (Site from Safety).		30 Oct 2020 00:20:47
User opened query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).		30 Oct 2020 00:20:37
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).		30 Oct 2020 00:17:48
User opened query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' (Site from Safety).		30 Oct 2020 00:16:37
User opened query 'PV Query: Please confirm the treatment dates in the narrative, as the event occurred in October, but treatment dates are reported as in September.' (Site from Safety).		30 Oct 2020 00:10:33
User opened query 'Per DM CLR: SAE narrative indicates OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS were given. However, there are no corresponding ConMed record to match these information. Please update to record these medications as appropriate. Otherwise, clarify.' (Site from DM).		29 Oct 2020 00:05:12
User opened query 'Per DM CLR: SAE Narrative indicates that the subject underwent 3 Spinal taps and an E. Coli test. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).		29 Oct 2020 00:04:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Per patient report over phone on 10/19/20 at 13:22, on 10/9/20 patient had symptoms of severe neck/back pain starting with no known trigger/incident. Wife drove patient to ER and patient was hospitalized for 5 nights. Per patient, 3 spinal taps were done, and an ecoli and COVID test performed, and all findings were negative. Per patient, oxycodone, an antibiotic, a muscle relaxant and Tylenol were prescribed, and morphine given via IV fluids. Patient was on IV fluids 9/10-9/14. Patient does recall all medication details. Patient feels much improved and last dose of antibiotics and pain medication was 10/16/2020. Medical records will be requested for more details.'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

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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 'I'	System	19 Oct 2020 21:59:37



**US3462091**

**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	19 Oct 2020 21:59:37

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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	19 Oct 2020 21:59:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 19:08:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 19:08:38
Data point term sent to Coder	System	15 Mar 2021 19:07:54
User entered 'Pneumonia'	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:10:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:10:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:10:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:10:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:10:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:10:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:10:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:10:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:10:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:10:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:10:43
User entered '06 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:10:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18



**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:10:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:10:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:10:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:17:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:17:06
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:17:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:10:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:10:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:10:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:19:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:19:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:19:00
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:19:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:19:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:19:00
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:19:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:19:00
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:19:00
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	15 Mar 2021 19:10:43
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Mar 2021 19:07:18
User entered '0'	(b) (4), (b) (6) (b) (4)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:10:43
User entered '0'		15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:19:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 19:19:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 19:19:09
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 19:07:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:07:18



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:38:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:06:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:07:18

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 19:10:43

**US3462091**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 19:10:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:38:10

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:00:25
User closed query 'Per ETRTR: According to SAE "Neck Pain" page, Concomitant Procedure was completed. Please complete data entry within Concomitant Procedures pages as applicable, thanks.' (Site from CRA).		15 Nov 2020 21:03:03
User closed query 'Per ETRTR: Please add Medication dosed details for SAE "Neck Pain", thanks.' (Site from CRA).		15 Nov 2020 21:03:02
Query 'Per ETRTR: According to SAE "Neck Pain" page, Concomitant Procedure was completed. Please complete data entry within Concomitant Procedures pages as applicable, thanks.' answered with 'ADDED' (Site from CRA).		07 Nov 2020 20:45:14
Query 'Per ETRTR: Please add Medication dosed details for SAE "Neck Pain", thanks.' answered with 'ADDED' (Site from CRA).		07 Nov 2020 20:45:12
User opened query 'Per ETRTR: According to SAE "Neck Pain" page, Concomitant Procedure was completed. Please complete data entry within Concomitant Procedures pages as applicable, thanks.' (Site from CRA).		22 Oct 2020 19:26:45
User opened query 'Per ETRTR: Please add Medication dosed details for SAE "Neck Pain", thanks.' (Site from CRA).		22 Oct 2020 19:25:00
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 22:26:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 22:26:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 22:26:53
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 22:26:49
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 22:26:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
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: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:30
Data point term sent to Coder	System	20 Oct 2020 00:00:24
Data point term sent to Coder	System	19 Oct 2020 23:59:20
User entered 'PREDNISONE'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'CHRONIC OBSTRUCTIVE PULMNARY DISEASE EXACERBATION' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Oct 2020 23:59:48
User entered 'CHRONIC OBSTRUCTIVE PULMNARY DISEASE'		19 Oct 2020 23:58:46



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '60'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 23:58:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 23:58:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 23:58:46

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '24 Jun 2020'	(b) (4), (b) (6)	19 Oct 2020 23:58:46



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '26 Jun 2020'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User entered '1'	System	19 Oct 2020 23:58:46

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User entered '1'	System	19 Oct 2020 23:58:46

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:40
User entered '804 (804)'	System	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:29
Data point term sent to Coder	System	20 Oct 2020 00:01:24
User entered 'PREDNISONE'	(b) (4), (b) (6)	20 Oct 2020 00:01:20



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE EXACERBATION'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '20'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '27 Jun 2020'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '29 Jun 2020'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User entered '1'	System	20 Oct 2020 00:01:20

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User entered '1'	System	20 Oct 2020 00:01:20



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:39:44
User entered '804 (804)'	System	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Oct 2020 00:03:26
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 Oct 2020 00:03:26
Data point term sent to Coder	System	20 Oct 2020 00:02:25
User entered 'METFORMIN'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'TYPE II DIABETES'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '2000'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:02:15



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:02:15

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:05:28
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 Oct 2020 00:05:28
Data point term sent to Coder	System	20 Oct 2020 00:04:28
User entered 'LOSARTAN'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'CONGESTIVE HEART FAILURE'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '25'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30



US3462091

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:38:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:03:30

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:03:30

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:03:30

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
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 Feb 2021 17:59:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:59:49
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	04 Feb 2021 17:59:31 04 Feb 2021 17:59:31
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)	20 Oct 2020 04:28:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:28:26
Data point term sent to Coder User entered 'ATORVASTATIN'	System (b) (4), (b) (6)	20 Oct 2020 00:04:29 20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM RQ: Thank you adding CONGESTIVE HEART FAILURE on MH page. However, the start date is not same. Please verify and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:28:29
Query 'Per DM RQ: Thank you adding CONGESTIVE HEART FAILURE on MH page. However, the start date is not same. Please verify and update.' answered with 'updated dates to match ' (Site from DM).		08 Feb 2021 18:18:40
User opened query 'Per DM RQ: Thank you adding CONGESTIVE HEART FAILURE on MH page. However, the start date is not same. Please verify and update.' (Site from DM).		08 Feb 2021 06:45:44
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		08 Feb 2021 06:45:44
User entered 'Congestive heart failure' reason for change: Data Entry Error		04 Feb 2021 17:59:31
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Added Medical condition' (Site from DM).		04 Feb 2021 17:56:00
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		20 Nov 2020 09:06:28
User entered 'CHRONIC HEART FAILURE'		20 Oct 2020 00:04:17



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '80'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:04:17

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:04:17

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:04:17

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: TORASEMIDE, PRODUCTSYNONYM: TORSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Oct 2020 00:07:27
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 Oct 2020 00:07:27
Data point term sent to Coder	System	20 Oct 2020 00:05:29
User entered 'TORSEMIDE'	(b) (4), (b) (6) [REDACTED] [REDACTED]	20 Oct 2020 00:05:13



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 12:05:04
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Updated' (Site from DM).		04 Feb 2021 18:09:30
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		23 Nov 2020 07:23:46
User entered 'BILATERAL LEG EDEMA'		20 Oct 2020 00:05:13

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '80'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:13

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:05:13

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:05:13



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Oct 2020 00:07:27
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 Oct 2020 00:07:27
Data point term sent to Coder	System	20 Oct 2020 00:06:31
User entered 'POTASSIUM'	(b) (4), (b) (6) (b) (4) (b) (4)	20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 12:04:21
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Unknown dose ' (Site from DM).		04 Feb 2021 18:22:36
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		23 Nov 2020 06:50:58
User entered '1'		20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:05:50



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:05:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:08:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:08:27
Data point term sent to Coder	System	20 Oct 2020 00:07:32
User entered 'ASPIRIN'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 06:47:07
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'Cardiac Prophylaxis' (Site from DM).		04 Feb 2021 18:01:41
User entered 'Yes (Y)' reason for change: Data Entry Error		04 Feb 2021 18:01:27
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).		20 Nov 2020 08:45:52
User entered 'No (N)'		20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'CARDIAC PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '81'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:06:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:06:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:06:50

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: ARFORMOTEROL TARTRATE, PRODUCTSYNONYM: BROVANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:09:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:09:28
Data point term sent to Coder	System	20 Oct 2020 00:08:33
User entered 'BROVANA'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'NEBULIZER'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN May 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:08:14

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:04:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:04:38
Data point term sent to Coder	System	20 Oct 2020 00:09:33
User entered 'QVAR'	(b) (4), (b) (6)	20 Oct 2020 00:09:09



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (d) (4), (b) (6)	05 Feb 2021 12:06:12
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Updated ' (Site from DM).		04 Feb 2021 18:23:17
User entered '40' reason for change: Data Entry Error		04 Feb 2021 18:23:07
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		23 Nov 2020 07:01:10
User entered '2'		20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per CDM re-query: MCG is equivalent to 'UG'. Please update to the pre defined option 'UG' instead of selecting the option 'Other'. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:37:52
Query 'Per CDM re-query: MCG is equivalent to 'UG'. Please update to the pre defined option 'UG' instead of selecting the option 'Other'. Thank you' answered with 'updated' (Site from DM).		08 Feb 2021 18:19:42
User entered 'ug (ug)' reason for change: Data Entry Error		08 Feb 2021 18:19:36
User opened query 'Per CDM re-query: MCG is equivalent to 'UG'. Please update to the pre defined option 'UG' instead of selecting the option 'Other'. Thank you' (Site from DM).		05 Feb 2021 12:06:09
User entered 'Other (OTHER)' reason for change: Data Entry Error		04 Feb 2021 18:23:07
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' canceled (Site from DM).		23 Nov 2020 07:01:04
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		23 Nov 2020 07:00:59
User entered 'puff (PUFF)'		20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:19:36
User entered 'MCG' reason for change: Data Entry Error		04 Feb 2021 18:23:07
User entered empty.		20 Oct 2020 00:09:09

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:09:09

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:09:09

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:09:09



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE, PRODUCTSYNONYM: STIOLTO RESPIMAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:57:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 04:57:32
Data point term sent to Coder	System	20 Oct 2020 00:10:34
User entered 'STIOLTO'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:10:23



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:10:23

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:10:23

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:04:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:04:56
Data point term sent to Coder	System	04 Feb 2021 18:03:46
Coding entries removed.	(b) (4), (b) (6)	04 Feb 2021 18:03:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:13:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:13:28
Data point term sent to Coder	System	20 Oct 2020 00:12:35
User entered 'JARDIANCE'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 12:07:25
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Updated' (Site from DM).		04 Feb 2021 18:03:09
User entered 'Congestive heart failure' reason for change: Data Entry Error		04 Feb 2021 18:03:01
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).		23 Nov 2020 03:52:10
User entered 'CHRONIC HEARY FAILURE'		20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '10'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '10 Jul 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:12:04

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:16:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:16:29
Data point term sent to Coder	System	07 Nov 2020 20:14:42
User entered 'morphine'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'No (N)'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'neck pain'		07 Nov 2020 20:14:35



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'I'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'Other (OTHER)'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'dose unknown'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'other (OTHER)'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'continuous'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'Intravenous (INTRAVENOUS)'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered empty.		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered '9 Oct 2020'		07 Nov 2020 20:14:35



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered '0'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'No (N)'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered '10 Oct 2020'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'No (N)'		07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User entered empty.	System	07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User entered empty.	System	07 Nov 2020 20:14:35

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:12
User entered empty.	System	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:17:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:17:29
Data point term sent to Coder	System	07 Nov 2020 20:20:45
User entered 'oxycodone'	(b) (4), (b) (6)	07 Nov 2020 20:19:58



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'No (N)'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'neck pain'		07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:31:29
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Unknown Dose due to no medical records sent to us, 3 attempts and no response ' (Site from DM).		08 Feb 2021 18:23:05
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		06 Jan 2021 16:58:18
DataPoint Verified.		18 Nov 2020 20:06:47
User entered '1'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'tablet (TABLET)'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered empty.		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:05:21
User entered 'as needed (PRN)' reason for change: Data Entry Error		04 Feb 2021 18:05:21
DataPoint Verified.		18 Nov 2020 20:06:47
User entered 'other (OTHER)'		07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4)	05 Feb 2021 12:07:54
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'uodated' (Site from DM)	(b) (4), (b) (6)	04 Feb 2021 18:05:30
User entered empty; reason for change Data Entry Error		04 Feb 2021 18:05:21
DataPoint Un-verified.		04 Feb 2021 18:04:31
User entered 'Daily as Needed' reason for change: Data Entry Error		04 Feb 2021 18:04:31
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).		06 Jan 2021 16:58:34
DataPoint Verified.		18 Nov 2020 20:06:47
User entered 'QIDPRN'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'Oral (ORAL)'		07 Nov 2020 20:19:58



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered empty.		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered '11 Oct 2020'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered '0'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'No (N)'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered '16 Oct 2020'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'No (N)'		07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User entered empty.	System	07 Nov 2020 20:19:58

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User entered empty.	System	07 Nov 2020 20:19:58



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 23:40:15
User entered empty.	System	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
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)	07 Nov 2020 20:23:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 20:23:20
Data point term sent to Coder	System	07 Nov 2020 20:21:46
User entered 'TYLENOL'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'No (N)'		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'NECK PAIN'		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered '650'		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'mg (mg)'		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered empty.		07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:04:56
User entered 'as needed (PRN)' reason for change: Data Entry Error		04 Feb 2021 18:04:56
DataPoint Verified.		18 Nov 2020 20:06:43
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Nov 2020 20:21:28
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:21:28
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Nov 2020 20:21:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Nov 2020 20:21:07



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4)	05 Feb 2021 12:08:00
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'updated' (Site from DM)	(b) (4), (b) (6)	04 Feb 2021 18:05:04
DataPoint Un-verified.		04 Feb 2021 18:04:56
User entered empty; reason for change Data Entry Error		04 Feb 2021 18:04:56
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).		06 Jan 2021 16:58:56
DataPoint Verified.		18 Nov 2020 20:06:43
User entered 'QIDPRN'		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'Oral (ORAL)'		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered empty.		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered '9 Oct 2020'		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered '0'		07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
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). User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 10:11:26
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 'updated (Site from DM). DataPoint Un-verified.	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	06 Apr 2021 22:55:08
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 19:19:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 19:19:36
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). User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 19:19:36
DataPoint Verified.	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	01 Apr 2021 12:33:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 19:41:34
	(b) (4), (b) (6)	18 Nov 2020 20:06:43
	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:55:08
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:19:36
Signature has been broken.		06 Apr 2021 19:19:36
User entered '29 Dec 2020' reason for change: Data Entry Error		06 Apr 2021 19:19:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered empty.		07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'No (N)'		07 Nov 2020 20:21:07



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User entered empty.	System	07 Nov 2020 20:21:28
User entered '1'	System	07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User entered empty.	System	07 Nov 2020 20:21:28
User entered '1'	System	07 Nov 2020 20:21:07

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:17:55
User entered empty.	System	07 Nov 2020 20:21:28
User entered '804 (804)'	System	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Please clarify what the name of this Muscle Relaxant is. ' (Site from CRA).	(b) (4)	
Query 'Please clarify what the name of this Muscle Relaxant is. ' answered with 'Unknown due to no medical records sent to us, 3 attempts and no response ' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:12:23
DataPoint Verified.		08 Feb 2021 18:23:35
User opened query 'Please clarify what the name of this Muscle Relaxant is. ' (Site from CRA).		18 Nov 2020 20:06:39
User coded data point as ATC:		18 Nov 2020 20:04:47
MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, PRODUCT: MUSCLE RELAXANTS - version	Coder Import (b) (4)	08 Nov 2020 11:16:30
WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version	Coder Import (b) (4)	08 Nov 2020 11:16:30
WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	07 Nov 2020 20:24:47
Data point term sent to Coder	System	07 Nov 2020 20:23:47
User entered 'MUSCLE RELAXANT'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'No (N)'		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'NECK PAIN'		07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:34:01
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count. Update the Dose and Dose Unit fields as appropriate.' answered with 'Unknown Dose due to no medical records sent to us, 3 attempts and no response ' (Site from DM).		08 Feb 2021 18:23:31
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		06 Jan 2021 16:59:27
DataPoint Verified.		18 Nov 2020 20:06:39
User entered '1'		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'tablet (TABLET)'		07 Nov 2020 20:23:11



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered empty.		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'as needed (PRN)'		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered empty.		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'Oral (ORAL)' reason for change: Data Entry Error		07 Nov 2020 20:23:55
User entered 'Other (OTHER)'		07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User closed query 'Route of administration is Other, however Other, specify is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:23:55
User opened query 'Route of administration is Other, however Other, specify is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:23:11
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered '9 Oct 2020'		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered '0'		07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding A has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User signature succeeded.	(b) (4)	07 Apr 2021 10:11:31
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 'updated (Site from DM). DataPoint Un-verified.	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	06 Apr 2021 22:55:08
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 19:21:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 19:21:09
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). User signature succeeded.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:21:09
DataPoint Verified.	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	01 Apr 2021 12:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:41:34
	(b) (4), (b) (6)	18 Nov 2020 20:06:39
	(b) (4), (b) (6)	07 Nov 2020 20:23:11



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:55:08
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '29 Dec 2020' reason for change: Data Entry Error	System	06 Apr 2021 19:21:24
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 19:21:24
DataPoint Un-verified.		
Signature has been broken.		06 Apr 2021 19:21:09
User entered '29 Dec 2021' reason for change: Data Entry Error		06 Apr 2021 19:21:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'No (N)'		07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User entered empty.	System	07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User entered empty.	System	07 Nov 2020 20:23:11

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:04
User entered empty.	System	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:38:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please review the Name of this medication and update to provide the generic component of the ANTIBIOTIC or provide the Trade name if known, as there are various ANTIBIOTIC available. Please update as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review the Name of this medication and update to provide the generic component of the ANTIBIOTIC or provide the Trade name if known, as there are various ANTIBIOTIC available. Please update as appropriate. Otherwise, clarify.' answered with 'Unknown due to no medical records sent to us, 3 attempts and no response ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:32:07  08 Feb 2021 18:24:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 08:49:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 08:49:51
Data point term sent to Coder	System	04 Feb 2021 18:16:11
Coding entries removed.	(b) (4), (b) (6)	04 Feb 2021 18:15:35
User opened query 'Per DM CLR: Please review the Name of this medication and update to provide the generic component of the ANTIBIOTIC or provide the Trade name if known, as there are various ANTIBIOTIC available. Please update as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.		06 Jan 2021 17:00:09  18 Nov 2020 20:06:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:07:29

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2045 of 2216

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Nov 2020 11:07:29
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	07 Nov 2020 20:26:49
User entered 'ANTIBIOTIC'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'No (N)'		07 Nov 2020 20:26:33



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:12:55
User closed query 'Per source Con Med Log, indication is noted as Neck Pain. Please clarify. ' (Site from CRA).		10 Feb 2021 18:12:51
Query 'Per source Con Med Log, indication is noted as Neck Pain. Please clarify. ' answered with 'Unknown due to no medical records sent to us, 3 attempts and no response ' (Site from CRA).		08 Feb 2021 18:24:26
DataPoint Un-verified.		04 Feb 2021 18:15:35
User entered 'Neck pain' reason for change: Data Entry Error		04 Feb 2021 18:15:35
DataPoint Verified.		18 Nov 2020 20:06:35
User opened query 'Per source Con Med Log, indication is noted as Neck Pain. Please clarify. ' (Site from CRA).		18 Nov 2020 20:02:51
User entered 'UNKNOWN'		07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:38:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per CDM: Per CCGs, if Dose per administration is unknown, then per the CCGs, it should be recorded as UNK. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:32:11
Query 'Per CDM: Per CCGs, if Dose per administration is unknown, then per the CCGs, it should be recorded as UNK. Please review and update as appropriate.' answered with 'Unknown Dose due to no medical records sent to us, 3 attempts and no response ' (Site from DM).		08 Feb 2021 18:24:33
DataPoint Verified.		18 Nov 2020 20:06:35
User opened query 'Per CDM: Per CCGs, if Dose per administration is unknown, then per the CCGs, it should be recorded as UNK. Please review and update as appropriate.' (Site from DM).		12 Nov 2020 12:17:00
User entered 'UNKNOWN'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'Other (OTHER)'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'UNKNOWN. WAITING FOR MEDICAL RECORDS.'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'unknown (UNKNOWN)'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered empty.		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'Oral (ORAL)'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered empty.		07 Nov 2020 20:26:33



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered '09 Oct 2020'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered '0'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'No (N)'		07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:26:53
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:26:53
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:26:33
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'No (N)'		07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User entered empty.	System	07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User entered empty.	System	07 Nov 2020 20:26:33

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:55:41
User entered empty.	System	07 Nov 2020 20:26:33



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 17:42:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 17:42:01
Data point term sent to Coder	System	31 Mar 2021 17:41:16
Data point term sent to Coder	System	31 Mar 2021 17:39:13
User entered 'Azithromycin'	(b) (4), (b) (6)	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 17:40:20
User entered 'Pneumonia' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 17:40:20
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 17:39:12
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '250' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 17:40:20
User entered '10'		31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'mg (mg)'	(b) (4), (b) (6)	31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:40:20
User entered 'three times daily (TID)'		31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User entered '1'	System	31 Mar 2021 17:40:20
User entered '3'	System	31 Mar 2021 17:39:12



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User entered '1'	System	31 Mar 2021 17:39:12

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:21
User entered '804 (804)'	System	31 Mar 2021 17:39:12

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
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: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 17:43:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 17:43:11
Data point term sent to Coder	System	31 Mar 2021 17:42:18
User entered 'Prednisone'	(b) (4), (b) (6)	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'Pneumonia'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '10'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21



**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21



US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:38:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User entered '3'	System	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User entered '1'	System	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:38:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:25
User entered '804 (804)'	System	31 Mar 2021 17:41:21

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 17:38:10**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:08:53

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:38:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:09:40

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:38:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'SPINAL TAP'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:09:40

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:09:40



US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:38:10

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:09:40

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 17:38:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:11:11
User entered '10 Oct 2020'		07 Nov 2020 20:10:02

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'SPINAL TAP'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:02

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:02

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:38:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:44
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:02

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:38:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:55

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:38:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please review procedure/surgery dates of this Procedure as it overlaps with Procedure #2: SPINAL TAP. Verify and update start/end dates or remove duplicate entry as necessary.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:39:57
Query 'Per DM CLR: Please review procedure/surgery dates of this Procedure as it overlaps with Procedure #2: SPINAL TAP. Verify and update start/end dates or remove duplicate entry as necessary.' answered with 'Unknown due to no medical records sent to us, 3 attempts and no response ' (Site from DM).		08 Feb 2021 18:26:06
User opened query 'Per DM CLR: Please review procedure/surgery dates of this Procedure as it overlaps with Procedure #2: SPINAL TAP. Verify and update start/end dates or remove duplicate entry as necessary.' (Site from DM).		02 Dec 2020 11:30:47
User entered 'SPINAL TAP'		07 Nov 2020 20:10:55

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:55



US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:38:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:55

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:38:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:43

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'NASAL SWAB'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:43

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:38:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:43

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:38:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:10:43

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 17:38:10**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:11:42

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'ECOLI TEST'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:11:42

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:11:42



US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:38:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:11:42

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 17:38:10**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:12:07

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Electrocardiogram'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:12:07

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:12:07

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 17:38:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:12:07

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 17:38:10**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:12:38

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:38:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:29:15
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' answered with 'IV Fluids is a non-drug ' (Site from DM).		08 Feb 2021 18:28:40
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' (Site from DM).		02 Dec 2020 11:31:03
User entered 'IV fluids'		07 Nov 2020 20:12:38

**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 17:38:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:12:38



**US3462091**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 17:38:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:12:38

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Gregg'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Lucksinger'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '1900 Cypress Creek Rd'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'Cedar Park'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'TX'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '78613'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.		06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
User entered '3'	System	05 Feb 2021 14:02:27
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Gregg'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Lucksinger'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '1900 Cypress Creek Rd'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'Cedar Park'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'TX'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '78613'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.		06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
User entered '3'	System	05 Feb 2021 14:02:27
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:38:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
User entered '20/Oct/2020 16:47'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:38:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.		06 Nov 2020 19:13:04
User entered '1'		20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Gregg'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Lucksinger'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '1900 Cypress Creek Rd'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'Cedar Park'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'TX'	(b) (4) System	08 Apr 2021 16:10:53



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '78613'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.		06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
User entered '3'	System	05 Feb 2021 14:02:27
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:38:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '09/Nov/2020 06:05'	(b) (4) System	09 Nov 2020 11:05:46

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:38:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:02:16
User entered 'I'		09 Nov 2020 11:05:46

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Gregg'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Lucksinger'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '1900 Cypress Creek Rd'	(b) (4) System	08 Apr 2021 16:10:53



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'Cedar Park'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'TX'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '78613'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.		06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
User entered '3'	System	05 Feb 2021 14:02:27
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:38:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered '05/Feb/2021 14:02'	(b) (4) System	05 Feb 2021 14:02:27

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:38:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:02:27

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40



**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Gregg'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40



US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:38:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 16:10:53
DataPoint Un-verified.	System	08 Apr 2021 16:10:53
Signature has been broken.	System	08 Apr 2021 16:10:53
User entered 'Lucksinger'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.		20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '1900 Cypress Creek Rd'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'Cedar Park'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'TX'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '78613'	(b) (4) System	08 Apr 2021 16:10:53

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.		06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:38:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 16:10:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:41:34
	(b) (4)	
User entered '3'	System	05 Feb 2021 14:02:27
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

**US3462091**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:38:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered '08/Apr/2021 12:10'	(b) (4) System	08 Apr 2021 16:10:53



US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:38:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:10:53