

US3442060 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:40:02

All time stamps listed in this document are displayed in GMT

US3442060

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

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[Participant ID](#)

US3442060

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

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US3442060

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" 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) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:53:56

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	HYPERTENSION
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 (4)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	LOW BONE DENSITY
Start date (dd MMM yyyy)	UN AUG 2019
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)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	OSTEOARTHRITIS: LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	OSTEOARTHRITIS: NECK
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	NECK SURGERY
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3442060

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	NECK SURGEY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Condition	NECK SURGERY
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: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:24 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:24
Height ( <i>xxx.x</i> )	62.0 in
Weight ( <i>xxx.x</i> )	151.8 lb
BMI ( <i>xxx.x</i> )	27.82264 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Date of assessment (dd MMM yyyy) 21 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1994

Date of last menstruation unknown False



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:53:56

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:53:56

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 187360

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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)	21 AUG 2020
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:24
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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)	21 AUG 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 13:15
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 12:38 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 12:38

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

11:45 (24 HR)

Collection date and time (derived)

21 AUG 2020 11:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:41	21 AUG 2020 11:41
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 13:12

PC Open Date & Time

21 AUG 2020 12:58

PC Close Date & Time

21 AUG 2020 15:28

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**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 96.8 °F

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

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

PC Time Stamp	22 AUG 2020 07:07
PC Open Date & Time	21 AUG 2020 16:23
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 20:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 19:34

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 18:14

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

25 AUG 2020 19:50

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

26 AUG 2020 17:22

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 20:58

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**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

21 AUG 2020 13:13

PC Open Date & Time

21 AUG 2020 12:58

PC Close Date & Time

21 AUG 2020 15:28

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**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

22 AUG 2020 07:11

PC Open Date & Time

21 AUG 2020 16:23

PC Close Date & Time

22 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**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

22 AUG 2020 20:59

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**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

23 AUG 2020 19:35

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**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

24 AUG 2020 18:14

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**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

25 AUG 2020 19:50

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**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

26 AUG 2020 17:22

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**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

27 AUG 2020 20:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**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 ☐

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 13:13
PC Open Date & Time	21 AUG 2020 12:58
PC Close Date & Time	21 AUG 2020 15:28

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**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 ☐

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 07:09
PC Open Date & Time	21 AUG 2020 16:23
PC Close Date & Time	22 AUG 2020 11:59



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**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 ☒

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 21:00
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:35
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**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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US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:16
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**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

58 of 2299

EAB) (1725)

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:51
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

60 of 2299

EAB) (1725)

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 17:22
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**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

62 of 2299

EAB) (1725)

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 21:00
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3442060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3442060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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)	21 SEP 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:05
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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)	21 SEP 2020
Time of assessment (00:00-23:59)	12:38 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:38
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3442060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 12:08 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 12:08

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

US3442060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

21 SEP 2020 11:10



US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	21 SEP 2020 11:15
Nasopharyngeal Swab 2	No		

US3442060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

21 SEP 2020 12:40

PC Open Date & Time

21 SEP 2020 12:28

PC Close Date & Time

21 SEP 2020 14:58

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	21 SEP 2020 17:23
PC Open Date & Time	21 SEP 2020 15:53
PC Close Date & Time	22 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**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

99.9 °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

22 SEP 2020 16:08

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 18:11

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**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

98.6 °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

24 SEP 2020 17:11

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

25 SEP 2020 21:53

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 00:40

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

27 SEP 2020 23:29

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**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

21 SEP 2020 12:40

PC Open Date & Time

21 SEP 2020 12:28

PC Close Date & Time

21 SEP 2020 14:58

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**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

21 SEP 2020 17:34

PC Open Date & Time

21 SEP 2020 15:53

PC Close Date & Time

22 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**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

22 SEP 2020 16:11

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 18:12

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**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

24 SEP 2020 17:11

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**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

25 SEP 2020 21:54

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**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

27 SEP 2020 00:41

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**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

27 SEP 2020 23:30

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**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 ☐

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 12:40
PC Open Date & Time	21 SEP 2020 12:28
PC Close Date & Time	21 SEP 2020 14:58

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**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 ☐

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 17:35
PC Open Date & Time	21 SEP 2020 15:53
PC Close Date & Time	22 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**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 ☒

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 16:11
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 18:13
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**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 ☒

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 17:12
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**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 ☒

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 21:54
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 00:41
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**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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US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 23:31
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3442060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3442060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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) \_\_\_\_\_

US3442060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

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.*

US3442060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

15:35 (24 HR)

Collection date and time (derived)

22 OCT 2020 15:35

US3442060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:56

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 19:42:28

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

28 OCT 2020 06:19:56

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 05:43:41

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59



US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 05:40:11

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 06:22:05

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 06:07:36

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 10:38:31
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

15 DEC 2020 12:01:12

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 00:02:11

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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 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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59
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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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 <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	07 JAN 2021 10:33:51
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

10 JAN 2021 08:43:08

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

17 JAN 2021 06:18:43

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

24 JAN 2021 05:42:11

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 07:19:04
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

07 FEB 2021 07:06:20

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 FEB 2021 03:41:20
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 02:07:36

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59



US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 21:52:14

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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	07 MAR 2021 07:22:41
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

14 MAR 2021 18:50:20

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 07:46:28

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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

29 MAR 2021 07:10:17

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 06:06:05

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 12:49:40

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 08:03:15

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:54:38

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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="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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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="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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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="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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

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30 DEC 2021 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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23 JAN 2022 00:01

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27 JAN 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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03 MAR 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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06 MAR 2022 00:01

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10 MAR 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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="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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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="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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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="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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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"/>

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**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 ☐ Yes ☐

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

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

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

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3442060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:40:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 21:52:31

US3442060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3442060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:31:59

Generated On: 09 Jun 2021 17:40:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:19:06

Generated On: 09 Jun 2021 17:40:02

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) \_\_\_\_\_



US3442060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:31:59

Generated On: 09 Jun 2021 17:40:02

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.*

US3442060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:31:59

Generated On: 09 Jun 2021 17:40:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 MAR 2021

Collection time (00:00-23:59)

14:49 (24 HR)

Collection date and time (derived)

9 MAR 2021 14:49

US3442060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:31:59

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3442060

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442060

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

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*

**US3442060**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:40:02**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442060

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:02

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"/>



**US3442060**

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

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

**Generated On: 09 Jun 2021 17:40:02**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3442060

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

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

Visit date (dd MMM yyyy)	7 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3442060

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:31:59

Generated On: 09 Jun 2021 17:40:02

Date of updated informed consent (dd MMM yyyy) 7 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 7 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3442060

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 JAN 2021

Collection time (00:00-23:59)

10:44 (24 HR)

Collection date and time (derived)

7 JAN 2021 10:44

US3442060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	10:41
Collection Date and Time (derived)	7 JAN 2021 10:41

US3442060

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:19:04

Generated On: 09 Jun 2021 17:40:02

AEID	
Adverse event	HYPERTENSIVE RETINOPATHY ( L )
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)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:19:04

Generated On: 09 Jun 2021 17:40:02

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



US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 15:19:04

Generated On: 09 Jun 2021 17:40:02

AEID	
Adverse event	WORSENING OF BLOOD PRESSURE
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)	17 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 15:19:04

Generated On: 09 Jun 2021 17:40:02

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

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Apr 2021 15:19:04

Generated On: 09 Jun 2021 17:40:02

AEID	USA-US017-2021-MRNA-1273-P30 1000009
Adverse event	WORSENING OF LEFT KNEE OSTEOARTHRITIS
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)	18 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	13 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Apr 2021 15:19:04

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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	
SUBJECT INFORMED THAT THEY WERE HOSPITALIZED ON 11FEB2021-13FEB2021 DUE TO LEFT KNEE REPLACEMENT SURGERY.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Data signed:** (b) (4) 13 Apr 2021 15:19:04

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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0

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

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

Yes ☒

No ☐

---

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

---

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN DEC 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication AMLODIPINE BESYLATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS: LEFT KNEE  
AND NECK

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 17:40:13

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication ALENDRONATE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication LOW BONE DENSITY

Dose per administration 70

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) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication BABY 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 (7)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 FEB 2021	
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 (8)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication IRON

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 65

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)

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication MAGNESIUM

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMMENT

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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 (11)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication MULTIVITAMIN 50+

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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 (12)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication VITAMIN C AND ZINC

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 60/15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication FISH OIL

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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 (14)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication TUMERIC

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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 (15)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication PROBIOTIC

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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 (16)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1500/1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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 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)	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 (17)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication FLULAVAL QUAD

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		2 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		2 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	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)	17 DEC 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"/>

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF LEFT KNEE  
OSTEOARTHRITIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRA-ARTICULAR	
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication AVASTIN (BEVACIZUMAB)

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSIVE RETINOPATHY  
(LEFT)

Dose per administration 1.25

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

	Intraocular	<input checked="" type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication KNEE PAIN (LEFT) SECONDARY  
TO LEFT KNEE REPLACEMENT

Dose per administration 5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

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



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication ARTHRITIS LEFT NECK AND KNEE

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

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

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

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

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

Name of Medication CINNAMON

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 17:40:13

Generated On: 09 Jun 2021 17:40:02

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

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:53:55

Generated On: 09 Jun 2021 17:40:02

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Apr 2021 15:19:06

Generated On: 09 Jun 2021 17:40:02

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 FEB 2021	LEFT TOTAL KNEE ARTHOROPLASTY	Medical History	
11 FEB 2021	CHEST PA LATERAL	Adverse Event	
11 FEB 2021	EKG	Adverse Event	
11 FEB 2021	RADIOLOGY - LEFT KNEE PORTABLE 2 VIEWS	Adverse Event	



US3442060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:40:02

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

US3442060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:40:02

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 ☐

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 15:19:06

Generated On: 09 Jun 2021 17:40:02

SAEID	USA-US017-2021-MRNA-1273-P301000009
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 15:19:06

Generated On: 09 Jun 2021 17:40:02

SAEID	USA-US017-2021-MRNA-1273-P301000009
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/MAR/2021 11:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 15:19:06

Generated On: 09 Jun 2021 17:40:02

SAEID	USA-US017-2021-MRNA-1273-P301000009
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	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/MAR/2021 09:20
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

US3442060 (Prod: Benchmark Research - Fort Worth)

**US3442060**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:40:02**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'US3442060'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 16:14:39

US3442060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:04



US3442060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 16:14:40

US3442060

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:04

**US3442060**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:40:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'SCRN'	System	21 Aug 2020 17:28:04

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered (b) (6) 1944' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	25 Nov 2020 04:40:29
User entered (b) (6) 1944' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 07:12:54
Comment added 'correct DOB is (b) (6) 1944'.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:42:15
User entered (b) (6) 1940'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:14:41

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4)	
	System	29 Sep 2020 07:12:54
Comment added 'dcf submitted to endpoint irt'.	(b) (4), (b) (6)	27 Aug 2020 14:25:27
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	21 Aug 2020 17:28:42
User entered '75'	Melody Dufrene (b) (4)	21 Aug 2020 17:28:30
	(b) (4)	

**US3442060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:40:02**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'YEARS'	System	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '75'	System	29 Sep 2020 07:12:54
User entered '79'	System	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Female (F)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30



US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'I'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30



US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:02

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:30

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Aug 2020'	System	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2020'	System	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Amendment 2 (2)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:42



US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:42

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 16:14:40

US3442060

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'I'	System	21 Aug 2020 17:28:49

US3442060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:40:02

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:28:49

US3442060

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:40:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:30:08

US3442060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:33:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:33:23
Data point term sent to Coder	System	21 Aug 2020 17:32:32
User entered 'ANEMIA'	Melody Dufrene (b) (4)	21 Aug 2020 17:31:45

US3442060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'UN UNK 2016'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:31:45



US3442060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:31:45

US3442060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:31:45

US3442060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:31:45

US3442060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:31:45

US3442060

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2016'	System	21 Aug 2020 17:31:45

**US3442060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2016'	System	21 Aug 2020 17:31:45

**US3442060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:31:45

**US3442060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:31:45



US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:34:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:34:17
Data point term sent to Coder	System	21 Aug 2020 17:33:35
User entered 'POST MENOPAUSAL'	Melody Dufrene (b) (4)	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'UN UNK 1994'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Melody Dufrene (b) (4)	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 1994'	System	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '1994'	System	21 Aug 2020 17:33:16



US3442060

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:33:16

**US3442060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:33:16

US3442060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:35:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:35:18
Data point term sent to Coder	System	21 Aug 2020 17:34:36
User entered 'HYPERTENSION'	Melody Dufrene (b) (4)	21 Aug 2020 17:34:00

US3442060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:34:00

US3442060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:34:00

US3442060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:34:00

US3442060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:34:00

US3442060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:34:00



US3442060

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2010'	System	21 Aug 2020 17:34:00

**US3442060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2010'	System	21 Aug 2020 17:34:00

**US3442060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:34:00

**US3442060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:34:00

US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:37:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:37:18
Data point term sent to Coder	System	21 Aug 2020 17:35:37
User entered 'HIGH CHOLESTEROL'	Melody Dufrene (b) (4)	21 Aug 2020 17:35:02

US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:02



US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:02

**US3442060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2010'	System	21 Aug 2020 17:35:02

US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2010'	System	21 Aug 2020 17:35:02

US3442060

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:35:02

**US3442060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:35:02

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Bone density decreased, LLT: Bone density decreased - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 17:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 17:27:49
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Bone density decreased, LLT: Bone density decreased - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 17:27:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 17:27:00
Data point term sent to Coder	System	09 Sep 2020 17:27:00
User closed query 'CDM-Coding:for coding purpose, please provide further information, related to LOW DENSITY OF BONE or Low density lipoprotein abnormal,please update the term accordingly.' (Site from System).	System	09 Sep 2020 17:26:06
Query 'CDM-Coding:for coding purpose, please provide further information, related to LOW DENSITY OF BONE or Low density lipoprotein abnormal,please update the term accordingly.' answered with 'corrected' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 17:26:06
Data point term sent to Coder	System	09 Sep 2020 17:25:58
User entered 'LOW bone DENSITY' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 17:25:57
User opened query 'CDM-Coding:for coding purpose, please provide further information, related to LOW DENSITY OF BONE or Low density lipoprotein abnormal,please update the term accordingly.' (Site from System).	Coder Import (b) (4)	09 Sep 2020 08:54:33
Data point term sent to Coder	System	21 Aug 2020 17:36:40
User entered 'LOW DENSITY'	Melody Dufrene (b) (4)	21 Aug 2020 17:35:54

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'UN Aug 2019'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:54



US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:54

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:54

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:54

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:35:54

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Aug 2019'	System	21 Aug 2020 17:35:54

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2019'	System	21 Aug 2020 17:35:54

US3442060

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:35:54

**US3442060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	21 Aug 2020 17:35:54



US3442060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 20:13:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 20:13:15
Data point term sent to Coder	System	07 Oct 2020 19:28:40
Coding entries removed.	Alma Guel (b) (4)	07 Oct 2020 19:28:20
User entered 'OSTEOARTHRITIS: Left KNEE'	Alma Guel (b) (4)	07 Oct 2020 19:28:20
reason for change: Data Entry Error		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 08:03:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 08:03:34
Data point term sent to Coder	System	05 Oct 2020 23:07:04
User entered 'osteoarthritis: knee'	(b) (4), (b) (6)	05 Oct 2020 23:06:57

US3442060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 2013'	(b) (4), (b) (6)	05 Oct 2020 23:06:57

US3442060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:06:57

**US3442060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:06:57

US3442060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:06:57

**US3442060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:06:57

US3442060

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2013'	System	05 Oct 2020 23:06:57

**US3442060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2013'	System	05 Oct 2020 23:06:57



**US3442060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	05 Oct 2020 23:06:57

**US3442060**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	05 Oct 2020 23:06:57

US3442060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of neck - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 23:08:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 23:08:24
Data point term sent to Coder	System	05 Oct 2020 23:08:05
User entered 'osteoarthritis: neck'	(b) (4), (b) (6)	05 Oct 2020 23:07:29

US3442060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:07:29

**US3442060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:07:29

US3442060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:07:29

US3442060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:07:29

**US3442060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:07:29



US3442060

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 1998'	System	05 Oct 2020 23:07:29

**US3442060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '1998'	System	05 Oct 2020 23:07:29

**US3442060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	05 Oct 2020 23:07:29

**US3442060**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered empty.	System	05 Oct 2020 23:07:29

US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Head, neck and oral cavity therapeutic procedures NEC, PT: Neck surgery, LLT: Neck surgery - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 23:08:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 23:08:24
Data point term sent to Coder	System	05 Oct 2020 23:08:05
User entered 'neck surgery'	(b) (4), (b) (6)	05 Oct 2020 23:07:53

US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 1998'	(b) (4), (b) (6)	05 Oct 2020 23:07:53

US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:07:53

US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:07:53



US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 1998'	(b) (4), (b) (6)	05 Oct 2020 23:07:53

**US3442060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:07:53

US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 1998'	System	05 Oct 2020 23:07:53

US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '1998'	System	05 Oct 2020 23:07:53

US3442060

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 1998'	System	05 Oct 2020 23:07:53

**US3442060**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '1998'	System	05 Oct 2020 23:07:53

US3442060

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Head, neck and oral cavity therapeutic procedures NEC, PT: Neck surgery, LLT: Neck surgery - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 08:06:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 08:06:32
Data point term sent to Coder	System	05 Oct 2020 23:09:06
User entered 'neck surgery'	(b) (4), (b) (6)	05 Oct 2020 23:08:09

US3442060

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 2006'	(b) (4), (b) (6)	05 Oct 2020 23:08:09



US3442060

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:08:09

US3442060

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:08:09

**US3442060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:40:02**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:08:09

**US3442060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:08:09

US3442060

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2006'	System	05 Oct 2020 23:08:09

**US3442060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:40:02**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2006'	System	05 Oct 2020 23:08:09

**US3442060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2006'	System	05 Oct 2020 23:08:09

**US3442060**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2006'	System	05 Oct 2020 23:08:09



US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Head, neck and oral cavity therapeutic procedures NEC, PT: Neck surgery, LLT: Neck surgery - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 23:09:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 23:09:25
Data point term sent to Coder	System	05 Oct 2020 23:09:06
User entered 'neck surgery'	(b) (4), (b) (6)	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 2013'	(b) (4), (b) (6)	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'un UNK 2013'	(b) (4), (b) (6)	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2013'	System	05 Oct 2020 23:08:34

**US3442060**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:40:02**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2013'	System	05 Oct 2020 23:08:34



**US3442060**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:40:02**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'Jan 2013'	System	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:40:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '2013'	System	05 Oct 2020 23:08:34

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '11:24'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '21 Aug 2020 11:24'	System	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '62.0' in	(b) (4)	
	Melody Dufrene (b) (4)	21 Aug 2020 17:37:54
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 17:28:49

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '151.8' lb	(b) (4)	
	Melody Dufrene (b) (4)	21 Aug 2020 17:37:54
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 17:28:49



US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
Amendment Manager: User entered '27.82264'	System	17 Sep 2020 00:18:22
User entered '27.8'	System	21 Aug 2020 17:37:54
DataPoint set to visible.	System	21 Aug 2020 17:28:49

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'kg/m2'	System	21 Aug 2020 17:37:54
DataPoint set to visible.	System	21 Aug 2020 17:28:49

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'bpm'	System	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54



US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'breaths/min'	System	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'mmHg'	System	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'mmHg'	System	21 Aug 2020 17:37:54

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26

US3442060

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26

US3442060

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:38:04



US3442060

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:38:04

US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13

US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13

US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13

US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13

US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13

US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13

US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'UN UNK 1994'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13



US3442060

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:40:02

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:13

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55



US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55



US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'I'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:39:55

US3442060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:19:45

US3442060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:19:45



US3442060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:19:45

**US3442060**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:40:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'VISIT1'	System	21 Aug 2020 20:19:45

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 17:14:23

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '187360'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 17:14:23

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 17:14:23

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:23:18

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:23:18

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:23:18



US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:23:18

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:23:18

US3442060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:02

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:34:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:01:33

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Pre-Dose (PREDOSE)'		21 Aug 2020 20:16:24



US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 20:17:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 20:17:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 20:17:38
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 20:16:24
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:17:38
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '11:24' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:17:38
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Aug 2020 11:24'	System	21 Aug 2020 20:17:38
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '96.9' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:17:38
User entered empty.		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:17:38
User entered empty.		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '68' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:17:38
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24



US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'bpm'	System	21 Aug 2020 20:17:38
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:17:38
User entered empty.		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'breaths/min'	System	21 Aug 2020 20:17:38
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '142' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:17:38
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Aug 2020 20:17:38
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '64' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:17:38
User entered empty.		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Aug 2020 20:17:38
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 20:16:24



US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Post-Dose (POSTDOSE)'		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
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	21 Aug 2020 20:19:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 20:19:26
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 20:16:24
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:19:26
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '13:15' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 20:19:26
User entered empty.		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Aug 2020 13:15'	System	21 Aug 2020 20:19:26
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 20:19:26
User entered empty.		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:19:26
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24



US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (D) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '65' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:19:26
User entered empty.		21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'bpm'	System	21 Aug 2020 20:19:26
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '12' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:19:26
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'breaths/min'	System	21 Aug 2020 20:19:26
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '126' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 20:19:26
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Aug 2020 20:19:26
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '73' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:19:26
User entered empty.		21 Aug 2020 20:16:24



US3442060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Aug 2020 20:19:26
User entered empty.	System	21 Aug 2020 20:16:24

US3442060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:21:35

US3442060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:21:35

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4)	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	21 Aug 2020 17:41:41



US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '12:38'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Aug 2020 12:38'	System	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Right Arm (RIGHT ARM)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'ONCE'	System	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 17:41:41

US3442060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:21:10

US3442060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:21:10

US3442060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '11:45'	(b) (4), (b) (6)	21 Aug 2020 20:21:10



US3442060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Aug 2020 11:45'	System	21 Aug 2020 20:21:10

US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 20:21:26

US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		21 Aug 2020 20:21:26

US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:21:26

US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '11:41'	(b) (4), (b) (6)	21 Aug 2020 20:21:26

US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Aug 2020 11:41'	System	21 Aug 2020 20:21:26

US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		21 Aug 2020 20:21:26

US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:21:26



US3442060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:21:26

**US3442060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:40:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered empty.	System	21 Aug 2020 20:21:26

US3442060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	31 Aug 2020 22:20:17

US3442060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '1'	System	31 Aug 2020 22:20:17

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:11:40', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bee9504c-ebef-4a86-9dc6-c0bac2776f2b' User entered 'Yes (Y)'	System	21 Aug 2020 18:12:17
	System	21 Aug 2020 18:12:17

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:11:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bee9504c-ebef-4a86-9dc6-c0bac2776f2b' User entered '97.2'	System	21 Aug 2020 18:12:17
	System	21 Aug 2020 18:12:17

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:12:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bee9504c-ebef-4a86-9dc6-c0bac2776f2b'	System	21 Aug 2020 18:12:17
User entered 'No (N)'	System	21 Aug 2020 18:12:17



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:12:14', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bee9504c-ebef-4a86-9dc6-c0bac2776f2b'	System	21 Aug 2020 18:12:17
User entered '21 Aug 2020 13:12'	System	21 Aug 2020 18:12:17

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 12:58'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 15:28'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:06:50', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e2fe8a9-c7f1-4150-8a0b-ab3a1efa7756'	System	22 Aug 2020 12:07:16
User entered 'Yes (Y)'	System	22 Aug 2020 12:07:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:07:01', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e2fe8a9-c7f1-4150-8a0b-ab3a1efa7756'	System	22 Aug 2020 12:07:16
User entered '96.8'	System	22 Aug 2020 12:07:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:07:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e2fe8a9-c7f1-4150-8a0b-ab3a1efa7756'	System	22 Aug 2020 12:07:16
User entered 'No (N)'	System	22 Aug 2020 12:07:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:07:14', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e2fe8a9-c7f1-4150-8a0b-ab3a1efa7756' User entered '22 Aug 2020 07:07'	System	22 Aug 2020 12:07:16
	System	22 Aug 2020 12:07:16



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 16:23'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 2'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:45:26', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '288268cd-9d4e-4771-859f-667dbf94dc49'	System	23 Aug 2020 01:46:16
User entered 'Yes (Y)'	System	23 Aug 2020 01:46:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:45:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '288268cd-9d4e-4771-859f-667dbf94dc49' User entered '98.1'	System	23 Aug 2020 01:46:16
	System	23 Aug 2020 01:46:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:46:02', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '288268cd-9d4e-4771-859f-667dbf94dc49'	System	23 Aug 2020 01:46:16
User entered 'No (N)'	System	23 Aug 2020 01:46:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:46:12', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '288268cd-9d4e-4771-859f-667dbf94dc49'	System	23 Aug 2020 01:46:16
User entered '22 Aug 2020 20:46'	System	23 Aug 2020 01:46:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 17:41:41



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 3'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:34:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '88b23ce3-b00c-47d3-a196-08f8865a7d1c'	System	24 Aug 2020 00:34:58
User entered 'Yes (Y)'	System	24 Aug 2020 00:34:58

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:34:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '88b23ce3-b00c-47d3-a196-08f8865a7d1c' User entered '96.1'	System	24 Aug 2020 00:34:58
	System	24 Aug 2020 00:34:58

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:34:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '88b23ce3-b00c-47d3-a196-08f8865a7d1c'	System	24 Aug 2020 00:34:58
User entered 'No (N)'	System	24 Aug 2020 00:34:58

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:34:56', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '88b23ce3-b00c-47d3-a196-08f8865a7d1c'	System	24 Aug 2020 00:34:58
User entered '23 Aug 2020 19:34'	System	24 Aug 2020 00:34:58

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:41:41



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 4'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:13:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4fac4f11-ad38-4182-9d82-5ca1f15fd7a8'	System	24 Aug 2020 23:14:16
User entered 'Yes (Y)'	System	24 Aug 2020 23:14:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:13:59', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4fac4f11-ad38-4182-9d82-5ca1f15fd7a8' User entered '98.3'	System	24 Aug 2020 23:14:16
	System	24 Aug 2020 23:14:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:14:07', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4fac4f11-ad38-4182-9d82-5ca1f15fd7a8'	System	24 Aug 2020 23:14:16
User entered 'No (N)'	System	24 Aug 2020 23:14:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:14:14', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4fac4f11-ad38-4182-9d82-5ca1f15fd7a8'	System	24 Aug 2020 23:14:16
User entered '24 Aug 2020 18:14'	System	24 Aug 2020 23:14:16

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 5'	System	21 Aug 2020 17:41:41



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:49:53', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'c98f75d6-cb4b-49cd-85e7-71d6ffa166e7'	System	26 Aug 2020 00:50:10
User entered 'Yes (Y)'	System	26 Aug 2020 00:50:10

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:49:59', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'c98f75d6-cb4b-49cd-85e7-71d6ffa166e7' User entered '97.5'	System	26 Aug 2020 00:50:10
	System	26 Aug 2020 00:50:10

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:04', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'c98f75d6-cb4b-49cd-85e7-71d6ffa166e7'	System	26 Aug 2020 00:50:10
User entered 'No (N)'	System	26 Aug 2020 00:50:10

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:07', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'c98f75d6-cb4b-49cd-85e7-71d6ffa166e7'	System	26 Aug 2020 00:50:10
User entered '25 Aug 2020 19:50'	System	26 Aug 2020 00:50:10

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 6'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:21:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0124adf7-e78a-454d-bfab-3c72dbb929c0'	System	26 Aug 2020 22:22:05
User entered 'Yes (Y)'	System	26 Aug 2020 22:22:05



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:21:55', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0124adf7-e78a-454d-bfab-3c72dbb929c0' User entered '98.7'	System	26 Aug 2020 22:22:05
	System	26 Aug 2020 22:22:05

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:21:59', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0124adf7-e78a-454d-bfab-3c72dbb929c0'	System	26 Aug 2020 22:22:05
User entered 'No (N)'	System	26 Aug 2020 22:22:05

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0124adf7-e78a-454d-bfab-3c72dbb929c0'	System	26 Aug 2020 22:22:05
User entered '26 Aug 2020 17:22'	System	26 Aug 2020 22:22:05

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 7'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:58:27', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '428e06b4-c483-4842-9627-d54cf5889683'	System	28 Aug 2020 01:58:45
User entered 'Yes (Y)'	System	28 Aug 2020 01:58:45

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:58:33', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '428e06b4-c483-4842-9627-d54cf5889683' User entered '97.1'	System	28 Aug 2020 01:58:45
	System	28 Aug 2020 01:58:45



US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:58:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '428e06b4-c483-4842-9627-d54cf5889683'	System	28 Aug 2020 01:58:45
User entered 'No (N)'	System	28 Aug 2020 01:58:45

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:58:43', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '428e06b4-c483-4842-9627-d54cf5889683'	System	28 Aug 2020 01:58:45
User entered '27 Aug 2020 20:58'	System	28 Aug 2020 01:58:45

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:12:34', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'dae05876-aea9-42b9-a6fb-b4fdc0f460d2'	System	21 Aug 2020 18:13:18
User entered 'None (1)'	System	21 Aug 2020 18:13:18

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:12:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'dae05876-aea9-42b9-a6fb-b4fdc0f460d2'	System	21 Aug 2020 18:13:18
User entered 'No (N)'	System	21 Aug 2020 18:13:18

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:12:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'dae05876-aea9-42b9-a6fb-b4fdc0f460d2'	System	21 Aug 2020 18:13:18
User entered 'No (N)'	System	21 Aug 2020 18:13:18



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:01', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'dae05876-aea9-42b9-a6fb-b4fdc0f460d2'	System	21 Aug 2020 18:13:18
User entered 'None (1)'	System	21 Aug 2020 18:13:18

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:13', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'dae05876-aea9-42b9-a6fb-b4fdc0f460d2'	System	21 Aug 2020 18:13:18
User entered '21 Aug 2020 13:13'	System	21 Aug 2020 18:13:18

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 12:58'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 15:28'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:10:15', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bf96be8f-fd0d-4716-8278-ffc83d6fb32a'	System	22 Aug 2020 12:11:05
User entered 'None (1)'	System	22 Aug 2020 12:11:05

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:10:19', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bf96be8f-fd0d-4716-8278-ffc83d6fb32a'	System	22 Aug 2020 12:11:05
User entered 'No (N)'	System	22 Aug 2020 12:11:05

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:10:52', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bf96be8f-fd0d-4716-8278-ffc83d6fb32a'	System	22 Aug 2020 12:11:05
User entered 'No (N)'	System	22 Aug 2020 12:11:05



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:10:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bf96be8f-fd0d-4716-8278-ffc83d6fb32a'	System	22 Aug 2020 12:11:05
User entered 'None (1)'	System	22 Aug 2020 12:11:05

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:11:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bf96be8f-fd0d-4716-8278-ffc83d6fb32a'	System	22 Aug 2020 12:11:05
User entered '22 Aug 2020 07:11'	System	22 Aug 2020 12:11:05

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 16:23'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 2'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:58:52', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '645cc90a-8964-42e8-a605-acef8f8f13a7'	System	23 Aug 2020 01:59:54
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 01:59:54

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:58:56', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '645cc90a-8964-42e8-a605-acef8f8f13a7'	System	23 Aug 2020 01:59:54
User entered 'No (N)'	System	23 Aug 2020 01:59:54

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:59:08', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '645cc90a-8964-42e8-a605-acef8f8f13a7'	System	23 Aug 2020 01:59:54
User entered 'No (N)'	System	23 Aug 2020 01:59:54



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:59:25', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '645cc90a-8964-42e8-a605-acef8f8f13a7'	System	23 Aug 2020 01:59:54
User entered 'None (1)'	System	23 Aug 2020 01:59:54

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:59:37', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '645cc90a-8964-42e8-a605-acef8f8f13a7'	System	23 Aug 2020 01:59:54
User entered '22 Aug 2020 20:59'	System	23 Aug 2020 01:59:54

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 3'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:10', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '68618770-def4-4e46-b739-ff67bbb57f29'	System	24 Aug 2020 00:35:31
User entered 'None (1)'	System	24 Aug 2020 00:35:31

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:14', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '68618770-def4-4e46-b739-ff67bbb57f29'	System	24 Aug 2020 00:35:31
User entered 'No (N)'	System	24 Aug 2020 00:35:31

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:19', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '68618770-def4-4e46-b739-ff67bbb57f29'	System	24 Aug 2020 00:35:31
User entered 'No (N)'	System	24 Aug 2020 00:35:31



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:26', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '68618770-def4-4e46-b739-ff67bbb57f29'	System	24 Aug 2020 00:35:31
User entered 'None (1)'	System	24 Aug 2020 00:35:31

**US3442060**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:40:02**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:29', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '68618770-def4-4e46-b739-ff67bbb57f29'	System	24 Aug 2020 00:35:31
User entered '23 Aug 2020 19:35'	System	24 Aug 2020 00:35:31

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 4'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:14:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '86669fcc-6f3b-442b-bb9e-5bfbd9f75992'	System	24 Aug 2020 23:14:52
User entered 'None (1)'	System	24 Aug 2020 23:14:52

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:14:24', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '86669fcc-6f3b-442b-bb9e-5bfbd9f75992'	System	24 Aug 2020 23:14:52
User entered 'No (N)'	System	24 Aug 2020 23:14:52

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:14:33', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '86669fcc-6f3b-442b-bb9e-5bfbd9f75992'	System	24 Aug 2020 23:14:52
User entered 'No (N)'	System	24 Aug 2020 23:14:52



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:14:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '86669fcc-6f3b-442b-bb9e-5bfbd9f75992'	System	24 Aug 2020 23:14:52
User entered 'None (1)'	System	24 Aug 2020 23:14:52

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:14:50', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '86669fcc-6f3b-442b-bb9e-5bfbd9f75992'	System	24 Aug 2020 23:14:52
User entered '24 Aug 2020 18:14'	System	24 Aug 2020 23:14:52

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 5'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:16', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9c8241ef-9c38-4a9f-b38d-9b95d7255246'	System	26 Aug 2020 00:50:43
User entered 'None (1)'	System	26 Aug 2020 00:50:43

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9c8241ef-9c38-4a9f-b38d-9b95d7255246'	System	26 Aug 2020 00:50:43
User entered 'No (N)'	System	26 Aug 2020 00:50:43

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:23', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9c8241ef-9c38-4a9f-b38d-9b95d7255246'	System	26 Aug 2020 00:50:43
User entered 'No (N)'	System	26 Aug 2020 00:50:43



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9c8241ef-9c38-4a9f-b38d-9b95d7255246'	System	26 Aug 2020 00:50:43
User entered 'None (1)'	System	26 Aug 2020 00:50:43

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9c8241ef-9c38-4a9f-b38d-9b95d7255246'	System	26 Aug 2020 00:50:43
User entered '25 Aug 2020 19:50'	System	26 Aug 2020 00:50:43

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 6'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:09', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '08a87d31-73bb-419b-9d93-86cf11ee7e02'	System	26 Aug 2020 22:22:28
User entered 'None (1)'	System	26 Aug 2020 22:22:28

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:14', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '08a87d31-73bb-419b-9d93-86cf11ee7e02'	System	26 Aug 2020 22:22:28
User entered 'No (N)'	System	26 Aug 2020 22:22:28

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:17', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '08a87d31-73bb-419b-9d93-86cf11ee7e02'	System	26 Aug 2020 22:22:28
User entered 'No (N)'	System	26 Aug 2020 22:22:28



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:21', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '08a87d31-73bb-419b-9d93-86cf11ee7e02'	System	26 Aug 2020 22:22:28
User entered 'None (1)'	System	26 Aug 2020 22:22:28

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:24', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '08a87d31-73bb-419b-9d93-86cf11ee7e02'	System	26 Aug 2020 22:22:28
User entered '26 Aug 2020 17:22'	System	26 Aug 2020 22:22:28

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 7'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:58:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '53626e11-92e4-4c5b-9e14-be371e6e74df' User entered 'None (1)'	System	28 Aug 2020 01:59:36
	System	28 Aug 2020 01:59:36

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:58:53', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '53626e11-92e4-4c5b-9e14-be371e6e74df' User entered 'No (N)'	System	28 Aug 2020 01:59:36
	System	28 Aug 2020 01:59:36

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:21', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '53626e11-92e4-4c5b-9e14-be371e6e74df' User entered 'No (N)'	System	28 Aug 2020 01:59:36
	System	28 Aug 2020 01:59:36



US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:30', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '53626e11-92e4-4c5b-9e14-be371e6e74df'	System	28 Aug 2020 01:59:36
User entered 'None (1)'	System	28 Aug 2020 01:59:36

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:34', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '53626e11-92e4-4c5b-9e14-be371e6e74df' User entered '27 Aug 2020 20:59'	System	28 Aug 2020 01:59:36
	System	28 Aug 2020 01:59:36

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:23', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered 'None (0)'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:26', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered 'None (0)'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:30', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered 'None (0)'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:32', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered 'None (0)'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:38', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered 'None (0)'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:42', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered 'None (0)'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:47', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered 'No (N)'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-21T13:13:50', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd5623f48-58c8-4a00-a808-f2c0d490617e' User entered '21 Aug 2020 13:13'	System	21 Aug 2020 18:13:53
	System	21 Aug 2020 18:13:53

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 12:58'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 15:28'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 17:41:41



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered 'No interference with activity (1)'	System	22 Aug 2020 12:09:51

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:17', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered 'None (0)'	System	22 Aug 2020 12:09:51

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:22', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered 'None (0)'	System	22 Aug 2020 12:09:51

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:28', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered 'None (0)'	System	22 Aug 2020 12:09:51

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:34', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered 'None (0)'	System	22 Aug 2020 12:09:51

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:38', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered 'None (0)'	System	22 Aug 2020 12:09:51

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:42', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered 'No (N)'	System	22 Aug 2020 12:09:51

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T07:09:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd84f7b37-52b1-47c0-858a-67d5f9c4e7d6'	System	22 Aug 2020 12:09:51
User entered '22 Aug 2020 07:09'	System	22 Aug 2020 12:09:51



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Aug 2020 16:23'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 2'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:59:52', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered 'None (0)'	System	23 Aug 2020 02:00:27

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T20:59:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered 'None (0)'	System	23 Aug 2020 02:00:27

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T21:00:02', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered 'None (0)'	System	23 Aug 2020 02:00:27

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T21:00:06', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered 'None (0)'	System	23 Aug 2020 02:00:27

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T21:00:09', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered 'None (0)'	System	23 Aug 2020 02:00:27



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T21:00:13', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered 'None (0)'	System	23 Aug 2020 02:00:27

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T21:00:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered 'No (N)'	System	23 Aug 2020 02:00:27

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-22T21:00:24', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6d3b5365-6f8a-459f-9d87-e30e747c0103'	System	23 Aug 2020 02:00:27
User entered '22 Aug 2020 21:00'	System	23 Aug 2020 02:00:27

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 3'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:34', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered 'None (0)'	System	24 Aug 2020 00:36:02

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:37', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered 'None (0)'	System	24 Aug 2020 00:36:02



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered 'None (0)'	System	24 Aug 2020 00:36:02

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered 'None (0)'	System	24 Aug 2020 00:36:02

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:47', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered 'None (0)'	System	24 Aug 2020 00:36:02

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered 'None (0)'	System	24 Aug 2020 00:36:02

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:55', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered 'No (N)'	System	24 Aug 2020 00:36:02

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-23T19:35:58', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '66d84066-7808-4a4e-af22-15e653784b76'	System	24 Aug 2020 00:36:02
User entered '23 Aug 2020 19:35'	System	24 Aug 2020 00:36:02

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:41:41



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 4'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:15:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered 'None (0)'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:15:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered 'None (0)'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:15:40', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered 'None (0)'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:15:42', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered 'None (0)'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:15:45', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered 'None (0)'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:15:48', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered 'None (0)'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:15:53', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered 'No (N)'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-24T18:16:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bd6c9645-75f2-4238-b28a-dbab996d011b' User entered '24 Aug 2020 18:16'	System	24 Aug 2020 23:16:03
	System	24 Aug 2020 23:16:03

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 5'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:48', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered 'None (0)'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered 'None (0)'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:55', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered 'None (0)'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:50:59', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered 'None (0)'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:51:02', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered 'None (0)'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:51:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered 'None (0)'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:51:08', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered 'No (N)'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-25T19:51:12', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4ad39e05-abe3-4325-b4d3-f8ca894c894b' User entered '25 Aug 2020 19:51'	System	26 Aug 2020 00:51:17
	System	26 Aug 2020 00:51:17

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 6'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:30', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6'	System	26 Aug 2020 22:22:52
User entered 'None (0)'	System	26 Aug 2020 22:22:52



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:33', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6'	System	26 Aug 2020 22:22:52
User entered 'None (0)'	System	26 Aug 2020 22:22:52

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:36', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6'	System	26 Aug 2020 22:22:52
User entered 'None (0)'	System	26 Aug 2020 22:22:52

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:38', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6' User entered 'None (0)'	System	26 Aug 2020 22:22:52
	System	26 Aug 2020 22:22:52

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6'	System	26 Aug 2020 22:22:52
User entered 'None (0)'	System	26 Aug 2020 22:22:52

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6'	System	26 Aug 2020 22:22:52
User entered 'None (0)'	System	26 Aug 2020 22:22:52

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:47', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6'	System	26 Aug 2020 22:22:52
User entered 'No (N)'	System	26 Aug 2020 22:22:52

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-26T17:22:50', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '751af801-0162-4209-b07d-2e151ed8dea6'	System	26 Aug 2020 22:22:52
User entered '26 Aug 2020 17:22'	System	26 Aug 2020 22:22:52

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 17:41:41



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 7'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:38', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac' User entered 'None (0)'	System	28 Aug 2020 02:00:18
	System	28 Aug 2020 02:00:18

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:43', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac' User entered 'None (0)'	System	28 Aug 2020 02:00:18
	System	28 Aug 2020 02:00:18

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:46', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac' User entered 'None (0)'	System	28 Aug 2020 02:00:18
	System	28 Aug 2020 02:00:18

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac' User entered 'None (0)'	System	28 Aug 2020 02:00:18
	System	28 Aug 2020 02:00:18

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:53', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac' User entered 'None (0)'	System	28 Aug 2020 02:00:18
	System	28 Aug 2020 02:00:18

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T20:59:56', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac' User entered 'None (0)'	System	28 Aug 2020 02:00:18
	System	28 Aug 2020 02:00:18



US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T21:00:01', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac'	System	28 Aug 2020 02:00:18
User entered 'No (N)'	System	28 Aug 2020 02:00:18

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-08-27T21:00:04', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd126f8c5-a4ed-4ce4-8dae-37a9c976f8ac'	System	28 Aug 2020 02:00:18
User entered '27 Aug 2020 21:00'	System	28 Aug 2020 02:00:18

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 17:41:41

US3442060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	31 Aug 2020 22:20:33

US3442060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '31 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	31 Aug 2020 22:20:33

US3442060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	Melody Dufrene (b) (4) (b) (4)	31 Aug 2020 22:20:33

US3442060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	31 Aug 2020 22:20:33



US3442060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 22:58:32

US3442060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'I'	System	02 Sep 2020 22:58:32

US3442060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:25:14

**US3442060**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:40:02**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 17:25:14

US3442060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 17:25:14

US3442060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:25:14

US3442060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 17:25:20

US3442060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'I'	System	04 Sep 2020 17:25:20



US3442060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 23:00:04

US3442060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 23:00:04

US3442060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 23:00:04

US3442060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 23:00:04

US3442060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 23:00:10

US3442060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'I'	System	14 Sep 2020 23:00:10

US3442060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:34:20

US3442060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:34:20



US3442060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:34:20

US3442060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'VISIT2'	System	21 Sep 2020 17:34:20

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Pre-Dose (PREDOSE)'		21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '11:05'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Sep 2020 11:05'	System	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '97.0' F	(b) (4), (b) (6)	21 Sep 2020 17:35:11



US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '63'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'bpm'	System	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '12'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'breaths/min'	System	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '153'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Sep 2020 17:35:11



US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '81'	(b) (4), (b) (6)	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Sep 2020 17:35:11

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Post-Dose (POSTDOSE)'		21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '12:38'	(b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Sep 2020 12:38'	System	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User closed query 'Per CDM: Please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 10:00:43
Query 'Per CDM: Please confirm if this result should be considered clinically significant or not.' answered with 'correct as entered. temp rechecked and remained the same. not clinically significant.' (Site from DM).		30 Sep 2020 17:04:35
User opened query 'Per CDM: Please confirm if this result should be considered clinically significant or not.' (Site from DM).		24 Sep 2020 14:09:40
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		24 Sep 2020 14:09:25
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as entered. temp rechecked and remained the same' (Site from System).		21 Sep 2020 17:45:15
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Sep 2020 17:44:57
User entered '96.5' F	(b) (4), (b) (6)	21 Sep 2020 17:44:57



US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '66'	(b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'bpm'	System	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '14'	(b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'breaths/min'	System	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '143'	(b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Sep 2020 17:44:57



US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '76'	(b) (4), (b) (6)	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'mmHg'	System	21 Sep 2020 17:44:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:35:29

US3442060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:35:29

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 17:11:31



US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '12:08'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Sep 2020 12:08'	System	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Right Arm (RIGHT ARM)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'ONCE'	System	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 17:11:31

US3442060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:35:41

US3442060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:35:41



US3442060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '11:10'	(b) (4), (b) (6)	21 Sep 2020 17:35:41

US3442060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Sep 2020 11:10'	System	21 Sep 2020 17:35:41

US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:35:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		21 Sep 2020 17:35:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:35:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '11:15'	(b) (4), (b) (6)	21 Sep 2020 17:35:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '21 Sep 2020 11:15'	System	21 Sep 2020 17:35:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		21 Sep 2020 17:35:57



US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 17:35:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:35:57

**US3442060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:40:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered empty.	System	21 Sep 2020 17:35:57

US3442060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:34:26

US3442060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '1'	System	21 Sep 2020 17:34:26

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:39:38', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e9a84569-9977-425b-b131-105fd6102670' User entered 'Yes (Y)'	System	21 Sep 2020 17:40:07
	System	21 Sep 2020 17:40:07

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:39:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e9a84569-9977-425b-b131-105fd6102670' User entered '96.5'	System	21 Sep 2020 17:40:07
	System	21 Sep 2020 17:40:07



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:39:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e9a84569-9977-425b-b131-105fd6102670'	System	21 Sep 2020 17:40:07
User entered 'No (N)'	System	21 Sep 2020 17:40:07

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e9a84569-9977-425b-b131-105fd6102670'	System	21 Sep 2020 17:40:07
User entered '21 Sep 2020 12:40'	System	21 Sep 2020 17:40:07

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 12:28'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 14:58'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:23:30', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f0f5d992-2c21-40ef-9b87-08ace81a69d1' User entered 'Yes (Y)'	System	21 Sep 2020 22:23:53
	System	21 Sep 2020 22:23:53

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:23:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f0f5d992-2c21-40ef-9b87-08ace81a69d1' User entered '97.7'	System	21 Sep 2020 22:23:53
	System	21 Sep 2020 22:23:53

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:23:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f0f5d992-2c21-40ef-9b87-08ace81a69d1' User entered 'No (N)'	System	21 Sep 2020 22:23:53
	System	21 Sep 2020 22:23:53



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:23:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f0f5d992-2c21-40ef-9b87-08ace81a69d1' User entered '21 Sep 2020 17:23'	System	21 Sep 2020 22:23:53
	System	21 Sep 2020 22:23:53

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 15:53'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 2'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:07:56', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3f0a433e-745c-4b3e-a7ff-9a5aea57b5bd' User entered 'Yes (Y)'	System	22 Sep 2020 21:08:18
	System	22 Sep 2020 21:08:18

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:08:07', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3f0a433e-745c-4b3e-a7ff-9a5aea57b5bd' User entered '99.9'	System	22 Sep 2020 21:08:18
	System	22 Sep 2020 21:08:18

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:08:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3f0a433e-745c-4b3e-a7ff-9a5aea57b5bd'	System	22 Sep 2020 21:08:18
User entered 'No (N)'	System	22 Sep 2020 21:08:18

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:08:16', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3f0a433e-745c-4b3e-a7ff-9a5aea57b5bd' User entered '22 Sep 2020 16:08'	System	22 Sep 2020 21:08:18
	System	22 Sep 2020 21:08:18



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 3'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:11:30', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '60fc17a9-de59-44d6-8087-fc4e42ad8fcf' User entered 'Yes (Y)'	System	23 Sep 2020 23:11:46
	System	23 Sep 2020 23:11:46

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:11:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '60fc17a9-de59-44d6-8087-fc4e42ad8fcf' User entered '97.1'	System	23 Sep 2020 23:11:46
	System	23 Sep 2020 23:11:46

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:11:40', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '60fc17a9-de59-44d6-8087-fc4e42ad8fcf' User entered 'No (N)'	System	23 Sep 2020 23:11:46
	System	23 Sep 2020 23:11:46

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:11:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '60fc17a9-de59-44d6-8087-fc4e42ad8fcf' User entered '23 Sep 2020 18:11'	System	23 Sep 2020 23:11:46
	System	23 Sep 2020 23:11:46

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:11:31



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 4'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '7a2642f4-082b-49c3-bcc7-30b3f18a0929'	System	24 Sep 2020 22:11:15
User entered 'Yes (Y)'	System	24 Sep 2020 22:11:15

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '7a2642f4-082b-49c3-bcc7-30b3f18a0929'	System	24 Sep 2020 22:11:15
User entered '98.6'	System	24 Sep 2020 22:11:15

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:08', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '7a2642f4-082b-49c3-bcc7-30b3f18a0929'	System	24 Sep 2020 22:11:15
User entered 'No (N)'	System	24 Sep 2020 22:11:15

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:12', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '7a2642f4-082b-49c3-bcc7-30b3f18a0929'	System	24 Sep 2020 22:11:15
User entered '24 Sep 2020 17:11'	System	24 Sep 2020 22:11:15

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:11:31



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 5'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:53:18', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3688bd5b-46a5-4183-a097-d65076f4e9aa' User entered 'Yes (Y)'	System	26 Sep 2020 02:53:45
	System	26 Sep 2020 02:53:45

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:53:37', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3688bd5b-46a5-4183-a097-d65076f4e9aa' User entered '96.9'	System	26 Sep 2020 02:53:45
	System	26 Sep 2020 02:53:45

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:53:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3688bd5b-46a5-4183-a097-d65076f4e9aa'	System	26 Sep 2020 02:53:45
User entered 'No (N)'	System	26 Sep 2020 02:53:45

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:53:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3688bd5b-46a5-4183-a097-d65076f4e9aa'	System	26 Sep 2020 02:53:45
User entered '25 Sep 2020 21:53'	System	26 Sep 2020 02:53:45

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 6'	System	21 Sep 2020 17:11:31



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:40:29', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'b6dceb65-dee3-408a-94ad-d409440b90b3' User entered 'Yes (Y)'	System	27 Sep 2020 05:40:44
	System	27 Sep 2020 05:40:44

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:40:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'b6dceb65-dee3-408a-94ad-d409440b90b3' User entered '96.8'	System	27 Sep 2020 05:40:44
	System	27 Sep 2020 05:40:44

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:40:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'b6dceb65-dee3-408a-94ad-d409440b90b3'	System	27 Sep 2020 05:40:44
User entered 'No (N)'	System	27 Sep 2020 05:40:44

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:40:42', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'b6dceb65-dee3-408a-94ad-d409440b90b3' User entered '27 Sep 2020 00:40'	System	27 Sep 2020 05:40:44
	System	27 Sep 2020 05:40:44

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 7'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:25', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f46b6acf-db53-4266-abf3-687e0293f9f0'	System	28 Sep 2020 04:29:43
User entered 'Yes (Y)'	System	28 Sep 2020 04:29:43



US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:33', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f46b6acf-db53-4266-abf3-687e0293f9f0' User entered '96.8'	System	28 Sep 2020 04:29:43
	System	28 Sep 2020 04:29:43

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:37', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f46b6acf-db53-4266-abf3-687e0293f9f0'	System	28 Sep 2020 04:29:43
User entered 'No (N)'	System	28 Sep 2020 04:29:43

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f46b6acf-db53-4266-abf3-687e0293f9f0'	System	28 Sep 2020 04:29:43
User entered '27 Sep 2020 23:29'	System	28 Sep 2020 04:29:43

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:13', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'ddc1d84e-8e71-46af-881f-aab32db343c0'	System	21 Sep 2020 17:40:34
User entered 'None (1)'	System	21 Sep 2020 17:40:34

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:16', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'ddc1d84e-8e71-46af-881f-aab32db343c0'	System	21 Sep 2020 17:40:34
User entered 'No (N)'	System	21 Sep 2020 17:40:34



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:19', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'ddc1d84e-8e71-46af-881f-aab32db343c0'	System	21 Sep 2020 17:40:34
User entered 'No (N)'	System	21 Sep 2020 17:40:34

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:25', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'ddc1d84e-8e71-46af-881f-aab32db343c0'	System	21 Sep 2020 17:40:34
User entered 'None (1)'	System	21 Sep 2020 17:40:34

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:30', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'ddc1d84e-8e71-46af-881f-aab32db343c0'	System	21 Sep 2020 17:40:34
User entered '21 Sep 2020 12:40'	System	21 Sep 2020 17:40:34

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 12:28'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 14:58'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:24:58', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e95dfe5-14c2-4056-a9ea-1b1efa3e5ccb' User entered 'None (1)'	System	21 Sep 2020 22:34:20
	System	21 Sep 2020 22:34:20

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:25:27', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e95dfe5-14c2-4056-a9ea-1b1efa3e5ccb' User entered 'No (N)'	System	21 Sep 2020 22:34:20
	System	21 Sep 2020 22:34:20



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e95dfe5-14c2-4056-a9ea-1b1efa3e5ccb' User entered 'No (N)'	System	21 Sep 2020 22:34:20
	System	21 Sep 2020 22:34:20

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:07', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e95dfe5-14c2-4056-a9ea-1b1efa3e5ccb' User entered 'None (1)'	System	21 Sep 2020 22:34:20
	System	21 Sep 2020 22:34:20

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:15', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e95dfe5-14c2-4056-a9ea-1b1efa3e5ccb' User entered '21 Sep 2020 17:34'	System	21 Sep 2020 22:34:20
	System	21 Sep 2020 22:34:20

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 15:53'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 2'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:08:31', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'be6b8abd-7766-4dba-b0fd-86baf436b333'	System	22 Sep 2020 21:11:24
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 21:11:24

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:08:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'be6b8abd-7766-4dba-b0fd-86baf436b333'	System	22 Sep 2020 21:11:24
User entered 'No (N)'	System	22 Sep 2020 21:11:24



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:10:13', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'be6b8abd-7766-4dba-b0fd-86baf436b333'	System	22 Sep 2020 21:11:24
User entered 'No (N)'	System	22 Sep 2020 21:11:24

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'be6b8abd-7766-4dba-b0fd-86baf436b333'	System	22 Sep 2020 21:11:24
User entered 'None (1)'	System	22 Sep 2020 21:11:24

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:22', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'be6b8abd-7766-4dba-b0fd-86baf436b333'	System	22 Sep 2020 21:11:24
User entered '22 Sep 2020 16:11'	System	22 Sep 2020 21:11:24

**US3442060**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:40:02**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 3'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:11:58', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3c29bd86-daf4-4033-ae8f-64345e381606'	System	23 Sep 2020 23:12:38
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 23:12:38

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3c29bd86-daf4-4033-ae8f-64345e381606'	System	23 Sep 2020 23:12:38
User entered 'No (N)'	System	23 Sep 2020 23:12:38



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:10', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3c29bd86-daf4-4033-ae8f-64345e381606'	System	23 Sep 2020 23:12:38
User entered 'Yes (Y)'	System	23 Sep 2020 23:12:38

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:22', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3c29bd86-daf4-4033-ae8f-64345e381606'	System	23 Sep 2020 23:12:38
User entered '1'	System	23 Sep 2020 23:12:38

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:28', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3c29bd86-daf4-4033-ae8f-64345e381606'	System	23 Sep 2020 23:12:38
User entered 'None (1)'	System	23 Sep 2020 23:12:38

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '3c29bd86-daf4-4033-ae8f-64345e381606'	System	23 Sep 2020 23:12:38
User entered '23 Sep 2020 18:12'	System	23 Sep 2020 23:12:38

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 4'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:19', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f67defbc-56d5-4176-9f1f-0b4eb888bf42'	System	24 Sep 2020 22:11:43
User entered 'None (1)'	System	24 Sep 2020 22:11:43



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:22', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f67defbc-56d5-4176-9f1f-0b4eb888bf42'	System	24 Sep 2020 22:11:43
User entered 'No (N)'	System	24 Sep 2020 22:11:43

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:26', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f67defbc-56d5-4176-9f1f-0b4eb888bf42'	System	24 Sep 2020 22:11:43
User entered 'No (N)'	System	24 Sep 2020 22:11:43

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:33', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f67defbc-56d5-4176-9f1f-0b4eb888bf42'	System	24 Sep 2020 22:11:43
User entered 'None (1)'	System	24 Sep 2020 22:11:43

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:37', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'f67defbc-56d5-4176-9f1f-0b4eb888bf42'	System	24 Sep 2020 22:11:43
User entered '24 Sep 2020 17:11'	System	24 Sep 2020 22:11:43

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 5'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:53:52', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'afc4f90c-79cb-4c44-a117-fab6811f1f22'	System	26 Sep 2020 02:54:10
User entered 'None (1)'	System	26 Sep 2020 02:54:10



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:53:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'afc4f90c-79cb-4c44-a117-fab6811f1f22'	System	26 Sep 2020 02:54:10
User entered 'No (N)'	System	26 Sep 2020 02:54:10

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:53:59', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'afc4f90c-79cb-4c44-a117-fab6811f1f22'	System	26 Sep 2020 02:54:10
User entered 'No (N)'	System	26 Sep 2020 02:54:10

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'afc4f90c-79cb-4c44-a117-fab6811f1f22'	System	26 Sep 2020 02:54:10
User entered 'None (1)'	System	26 Sep 2020 02:54:10

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:07', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'afc4f90c-79cb-4c44-a117-fab6811f1f22'	System	26 Sep 2020 02:54:10
User entered '25 Sep 2020 21:54'	System	26 Sep 2020 02:54:10

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 6'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:40:46', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '16d0d322-c364-4caf-b90d-614b9c860e67'	System	27 Sep 2020 05:41:06
User entered 'None (1)'	System	27 Sep 2020 05:41:06



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:40:50', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '16d0d322-c364-4caf-b90d-614b9c860e67'	System	27 Sep 2020 05:41:06
User entered 'No (N)'	System	27 Sep 2020 05:41:06

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:40:53', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '16d0d322-c364-4caf-b90d-614b9c860e67'	System	27 Sep 2020 05:41:06
User entered 'No (N)'	System	27 Sep 2020 05:41:06

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:01', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '16d0d322-c364-4caf-b90d-614b9c860e67'	System	27 Sep 2020 05:41:06
User entered 'None (1)'	System	27 Sep 2020 05:41:06

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:04', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '16d0d322-c364-4caf-b90d-614b9c860e67' User entered '27 Sep 2020 00:41'	System	27 Sep 2020 05:41:06
	System	27 Sep 2020 05:41:06

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 7'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:46', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '096aee90-7436-4e6f-af76-d4e08c59cedd'	System	28 Sep 2020 04:30:08
User entered 'None (1)'	System	28 Sep 2020 04:30:08



US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:50', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '096aee90-7436-4e6f-af76-d4e08c59cedd' User entered 'No (N)'	System	28 Sep 2020 04:30:08
	System	28 Sep 2020 04:30:08

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:54', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '096aee90-7436-4e6f-af76-d4e08c59cedd' User entered 'No (N)'	System	28 Sep 2020 04:30:08
	System	28 Sep 2020 04:30:08

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:29:59', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '096aee90-7436-4e6f-af76-d4e08c59cedd'	System	28 Sep 2020 04:30:08
User entered 'None (1)'	System	28 Sep 2020 04:30:08

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:30:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '096aee90-7436-4e6f-af76-d4e08c59cedd' User entered '27 Sep 2020 23:30'	System	28 Sep 2020 04:30:08
	System	28 Sep 2020 04:30:08

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d' User entered 'None (0)'	System	21 Sep 2020 17:41:01
	System	21 Sep 2020 17:41:01



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:43', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d' User entered 'None (0)'	System	21 Sep 2020 17:41:01
	System	21 Sep 2020 17:41:01

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:47', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d' User entered 'None (0)'	System	21 Sep 2020 17:41:01
	System	21 Sep 2020 17:41:01

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d' User entered 'None (0)'	System	21 Sep 2020 17:41:01
	System	21 Sep 2020 17:41:01

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d' User entered 'None (0)'	System	21 Sep 2020 17:41:01
	System	21 Sep 2020 17:41:01

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:53', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d' User entered 'None (0)'	System	21 Sep 2020 17:41:01
	System	21 Sep 2020 17:41:01

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:55', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d' User entered 'No (N)'	System	21 Sep 2020 17:41:01
	System	21 Sep 2020 17:41:01

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T12:40:58', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e2b88ded-a764-4416-9ede-c7c772fe794d'	System	21 Sep 2020 17:41:01
User entered '21 Sep 2020 12:40'	System	21 Sep 2020 17:41:01

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 12:28'	System	21 Sep 2020 17:11:31



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 14:58'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered 'None (0)'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:23', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered 'None (0)'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered 'None (0)'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered 'None (0)'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:34:47', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered 'None (0)'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:35:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered 'None (0)'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:35:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered 'No (N)'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-21T17:35:15', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e469f43-bf13-4d73-a1d0-dede74e06aa9' User entered '21 Sep 2020 17:35'	System	21 Sep 2020 22:35:19
	System	21 Sep 2020 22:35:19

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '21 Sep 2020 15:53'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 2'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:28', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647'	System	22 Sep 2020 21:12:00
User entered 'None (0)'	System	22 Sep 2020 21:12:00

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:32', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647'	System	22 Sep 2020 21:12:00
User entered 'None (0)'	System	22 Sep 2020 21:12:00

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647'	System	22 Sep 2020 21:12:00
User entered 'None (0)'	System	22 Sep 2020 21:12:00



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647' User entered 'None (0)'	System	22 Sep 2020 21:12:00
	System	22 Sep 2020 21:12:00

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:42', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647'	System	22 Sep 2020 21:12:00
User entered 'None (0)'	System	22 Sep 2020 21:12:00

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:46', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647'	System	22 Sep 2020 21:12:00
User entered 'None (0)'	System	22 Sep 2020 21:12:00

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:54', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647'	System	22 Sep 2020 21:12:00
User entered 'No (N)'	System	22 Sep 2020 21:12:00

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-22T16:11:58', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1e20b550-1499-438a-9dd9-03097e117647'	System	22 Sep 2020 21:12:00
User entered '22 Sep 2020 16:11'	System	22 Sep 2020 21:12:00

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 3'	System	21 Sep 2020 17:11:31



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:40', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac' User entered 'None (0)'	System	23 Sep 2020 23:13:06
	System	23 Sep 2020 23:13:06

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:43', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac' User entered 'None (0)'	System	23 Sep 2020 23:13:06
	System	23 Sep 2020 23:13:06

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:47', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac' User entered 'None (0)'	System	23 Sep 2020 23:13:06
	System	23 Sep 2020 23:13:06

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:50', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac' User entered 'None (0)'	System	23 Sep 2020 23:13:06
	System	23 Sep 2020 23:13:06

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:52', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac' User entered 'None (0)'	System	23 Sep 2020 23:13:06
	System	23 Sep 2020 23:13:06

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:55', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac' User entered 'None (0)'	System	23 Sep 2020 23:13:06
	System	23 Sep 2020 23:13:06

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:12:58', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac'	System	23 Sep 2020 23:13:06
User entered 'No (N)'	System	23 Sep 2020 23:13:06

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-23T18:13:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '031ab5a0-8f09-4e70-9bda-86430f17b1ac' User entered '23 Sep 2020 18:13'	System	23 Sep 2020 23:13:06
	System	23 Sep 2020 23:13:06



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 4'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63' User entered 'None (0)'	System	24 Sep 2020 22:12:03
	System	24 Sep 2020 22:12:03

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63' User entered 'None (0)'	System	24 Sep 2020 22:12:03
	System	24 Sep 2020 22:12:03

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:47', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63' User entered 'None (0)'	System	24 Sep 2020 22:12:03
	System	24 Sep 2020 22:12:03

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63' User entered 'None (0)'	System	24 Sep 2020 22:12:03
	System	24 Sep 2020 22:12:03

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:52', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63' User entered 'None (0)'	System	24 Sep 2020 22:12:03
	System	24 Sep 2020 22:12:03



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:54', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63'	System	24 Sep 2020 22:12:03
User entered 'None (0)'	System	24 Sep 2020 22:12:03

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:11:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63'	System	24 Sep 2020 22:12:03
User entered 'No (N)'	System	24 Sep 2020 22:12:03

**US3442060**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:40:02**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-24T17:12:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '817e707c-47ec-487c-a3bf-5d16653f5a63' User entered '24 Sep 2020 17:12'	System	24 Sep 2020 22:12:03
	System	24 Sep 2020 22:12:03

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 5'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:18', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered 'None (0)'	System	26 Sep 2020 02:54:48

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:21', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered 'None (0)'	System	26 Sep 2020 02:54:48



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:24', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered 'None (0)'	System	26 Sep 2020 02:54:48

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:26', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered 'None (0)'	System	26 Sep 2020 02:54:48

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:29', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered 'None (0)'	System	26 Sep 2020 02:54:48

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:31', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered 'None (0)'	System	26 Sep 2020 02:54:48

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered 'No (N)'	System	26 Sep 2020 02:54:48

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-25T21:54:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e63bd297-4fb0-4163-a512-8d52436fc233'	System	26 Sep 2020 02:54:48
User entered '25 Sep 2020 21:54'	System	26 Sep 2020 02:54:48

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:11:31



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 6'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:08', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc' User entered 'None (0)'	System	27 Sep 2020 05:41:31
	System	27 Sep 2020 05:41:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc' User entered 'None (0)'	System	27 Sep 2020 05:41:31
	System	27 Sep 2020 05:41:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:14', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc' User entered 'None (0)'	System	27 Sep 2020 05:41:31
	System	27 Sep 2020 05:41:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:16', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc' User entered 'None (0)'	System	27 Sep 2020 05:41:31
	System	27 Sep 2020 05:41:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc' User entered 'None (0)'	System	27 Sep 2020 05:41:31
	System	27 Sep 2020 05:41:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:22', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc' User entered 'None (0)'	System	27 Sep 2020 05:41:31
	System	27 Sep 2020 05:41:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:26', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc'	System	27 Sep 2020 05:41:31
User entered 'No (N)'	System	27 Sep 2020 05:41:31



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T00:41:28', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e8658f23-8e42-4eba-a54d-356c6cb2d7cc'	System	27 Sep 2020 05:41:31
User entered '27 Sep 2020 00:41'	System	27 Sep 2020 05:41:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Sep 2020 17:11:31
User entered 'Day 7'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:30:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2'	System	28 Sep 2020 04:31:18
User entered 'None (0)'	System	28 Sep 2020 04:31:18

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:30:35', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2'	System	28 Sep 2020 04:31:18
User entered 'None (0)'	System	28 Sep 2020 04:31:18

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:30:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2' User entered 'None (0)'	System	28 Sep 2020 04:31:18
	System	28 Sep 2020 04:31:18

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:30:44', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2' User entered 'None (0)'	System	28 Sep 2020 04:31:18
	System	28 Sep 2020 04:31:18



US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:30:55', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2' User entered 'None (0)'	System	28 Sep 2020 04:31:18
	System	28 Sep 2020 04:31:18

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:30:58', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2'	System	28 Sep 2020 04:31:18
User entered 'None (0)'	System	28 Sep 2020 04:31:18

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:31:06', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2'	System	28 Sep 2020 04:31:18
User entered 'No (N)'	System	28 Sep 2020 04:31:18

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-09-27T23:31:16', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '5bc2627b-a5c3-4b4a-be85-fe6177fab9d2'	System	28 Sep 2020 04:31:18
User entered '27 Sep 2020 23:31'	System	28 Sep 2020 04:31:18

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:11:31

US3442060

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:40:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:11:31

US3442060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 15:30:15

US3442060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 15:30:15



US3442060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 15:30:15

US3442060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:30:15

US3442060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:30:20

US3442060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '1'	System	28 Sep 2020 15:30:20

US3442060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:02:53

US3442060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 23:02:53

US3442060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 23:02:53

US3442060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:02:53



US3442060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:02:57

US3442060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'I'	System	05 Oct 2020 23:02:57

US3442060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:23:36

US3442060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '12 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 21:23:36

US3442060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 21:23:36

US3442060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:23:36

US3442060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:23:41

US3442060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'I'	System	14 Oct 2020 21:23:41



US3442060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:01

US3442060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '22 Oct 2020'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:01

US3442060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Clinic (Clinic)'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:01

US3442060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered 'VISIT3'	System	22 Oct 2020 21:02:01

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4)	
	John Villegas (b) (4)	22 Oct 2020 21:02:13
	(b) (4)	

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered empty.	System	22 Oct 2020 21:02:13



US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered empty.	System	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered empty.	System	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13



US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered empty.	System	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered empty.	System	22 Oct 2020 21:02:13

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28

US3442060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28

US3442060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4)	
	John Villegas (b) (4)	22 Oct 2020 21:02:15
	(b) (4)	

US3442060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered empty.	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:15

US3442060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:25



US3442060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: : Sample dated 22Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day 57 Visit with date 22Oct2020in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:55:37
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: : Sample dated 22Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day 57 Visit with date 22Oct2020in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Please clarify as dates are exactly the same ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:45:49
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: : Sample dated 22Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day 57 Visit with date 22Oct2020in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:40:52
User entered '22 Oct 2020'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:25

US3442060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered '15:35'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:25

US3442060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '22 Oct 2020 15:35'	System	22 Oct 2020 21:02:25

US3442060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	22 Oct 2020 21:02:29

US3442060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '1'	System	22 Oct 2020 21:02:29

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 64'	System	21 Aug 2020 17:41:41

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-10-21T19:42:03', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'c88d8134-be80-4367-9c95-4f1460b28b72'	System	22 Oct 2020 00:42:33
User entered 'No (N)'	System	22 Oct 2020 00:42:33

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-10-21T19:42:14', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'c88d8134-be80-4367-9c95-4f1460b28b72'	System	22 Oct 2020 00:42:33
User entered 'No (N)'	System	22 Oct 2020 00:42:33



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-10-21T19:42:28', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'c88d8134-be80-4367-9c95-4f1460b28b72'	System	22 Oct 2020 00:42:33
User entered '21 Oct 2020 19:42:28'	System	22 Oct 2020 00:42:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 17:41:41

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 71'	System	21 Aug 2020 17:41:41

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-10-28T06:19:37', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'fec70b71-c1ad-4869-bc08-d8374dc4274a'	System	28 Oct 2020 11:19:57
User entered 'No (N)'	System	28 Oct 2020 11:19:57

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-10-28T06:19:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'fec70b71-c1ad-4869-bc08-d8374dc4274a'	System	28 Oct 2020 11:19:57
User entered 'No (N)'	System	28 Oct 2020 11:19:57

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-10-28T06:19:56', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'fec70b71-c1ad-4869-bc08-d8374dc4274a' User entered '28 Oct 2020 06:19:56'	System	28 Oct 2020 11:19:57
	System	28 Oct 2020 11:19:57

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 17:41:41



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 78'	System	21 Aug 2020 17:41:41

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-04T05:43:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '2e007a4f-6696-4661-9614-a588c39f8b18'	System	04 Nov 2020 11:43:43
User entered 'No (N)'	System	04 Nov 2020 11:43:43

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-04T05:42:12', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '2e007a4f-6696-4661-9614-a588c39f8b18'	System	04 Nov 2020 11:43:43
User entered 'No (N)'	System	04 Nov 2020 11:43:43

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-04T05:43:41', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '2e007a4f-6696-4661-9614-a588c39f8b18' User entered '04 Nov 2020 05:43:41'	System	04 Nov 2020 11:43:43
	System	04 Nov 2020 11:43:43

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 17:41:41

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 17:41:41

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered 'Day 92'	System	21 Aug 2020 17:41:41



US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-18T05:39:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1257aaf0-f5cf-4b9f-811d-667f800b9e3b'	System	18 Nov 2020 11:40:13
User entered 'No (N)'	System	18 Nov 2020 11:40:13

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-18T05:40:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1257aaf0-f5cf-4b9f-811d-667f800b9e3b'	System	18 Nov 2020 11:40:13
User entered 'No (N)'	System	18 Nov 2020 11:40:13

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-18T05:40:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '1257aaf0-f5cf-4b9f-811d-667f800b9e3b' User entered '18 Nov 2020 05:40:11'	System	18 Nov 2020 11:40:13
	System	18 Nov 2020 11:40:13

US3442060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 17:41:41

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:07:59
Data entry locked.	System	21 Aug 2020 17:41:41
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 17:41:41

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-25T06:21:49', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '704811c9-e35d-4a3f-8f2a-4a88e91bc5c5'	System	25 Nov 2020 12:22:08
User entered 'No (N)'	System	25 Nov 2020 12:22:08

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-25T06:21:57', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '704811c9-e35d-4a3f-8f2a-4a88e91bc5c5'	System	25 Nov 2020 12:22:08
User entered 'No (N)'	System	25 Nov 2020 12:22:08



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-25T06:22:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '704811c9-e35d-4a3f-8f2a-4a88e91bc5c5'	System	25 Nov 2020 12:22:08
User entered '25 Nov 2020 06:22:05'	System	25 Nov 2020 12:22:08

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-29T06:07:08', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '652cb22e-bd15-45a8-a2d3-2467721abf59'	System	29 Nov 2020 12:07:39
User entered 'No (N)'	System	29 Nov 2020 12:07:39

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-29T06:07:25', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '652cb22e-bd15-45a8-a2d3-2467721abf59'	System	29 Nov 2020 12:07:39
User entered 'No (N)'	System	29 Nov 2020 12:07:39

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-11-29T06:07:36', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '652cb22e-bd15-45a8-a2d3-2467721abf59'	System	29 Nov 2020 12:07:39
User entered '29 Nov 2020 06:07:36'	System	29 Nov 2020 12:07:39

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:41:33

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

[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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-06T10:38:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6c288ef9-436e-4c6b-b38b-072da8d50990' User entered 'No (N)'	System	06 Dec 2020 16:38:43
	System	06 Dec 2020 16:38:43

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Have you been exposed to someone with 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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-06T10:38:12', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6c288ef9-436e-4c6b-b38b-072da8d50990' User entered 'Yes (Y)'	System	06 Dec 2020 16:38:43
	System	06 Dec 2020 16:38:43

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Please 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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-06T10:38:22', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6c288ef9-436e-4c6b-b38b-072da8d50990'	System	06 Dec 2020 16:38:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 16:38:43

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-06T10:38:31', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '6c288ef9-436e-4c6b-b38b-072da8d50990' User entered '06 Dec 2020 10:38:31'	System	06 Dec 2020 16:38:43
	System	06 Dec 2020 16:38:43

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-15T12:01:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '05d1d1cb-db67-47f4-b7f7-e408916f0af9'	System	15 Dec 2020 18:01:15
User entered 'No (N)'	System	15 Dec 2020 18:01:15

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-15T12:01:08', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '05d1d1cb-db67-47f4-b7f7-e408916f0af9' User entered 'No (N)'	System	15 Dec 2020 18:01:15
	System	15 Dec 2020 18:01:15

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-15T12:01:12', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '05d1d1cb-db67-47f4-b7f7-e408916f0af9' User entered '15 Dec 2020 12:01:12'	System	15 Dec 2020 18:01:15
	System	15 Dec 2020 18:01:15

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-20T00:01:53', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'a44dc22f-c4af-49ae-9f07-d9b7ca7c24d9' User entered 'No (N)'	System	20 Dec 2020 06:02:34
	System	20 Dec 2020 06:02:34



US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-20T00:02:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'a44dc22f-c4af-49ae-9f07-d9b7ca7c24d9' User entered 'No (N)'	System	20 Dec 2020 06:02:34

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EE8B07B4-B5FB-45DD-ACA5-394984DCE6C1)', Time: '2020-12-20T00:02:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'a44dc22f-c4af-49ae-9f07-d9b7ca7c24d9' User entered '20 Dec 2020 00:02:11'	System	20 Dec 2020 06:02:34
	System	20 Dec 2020 06:02:34

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:41:33



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-07T10:32:54', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '566d7ff9-84f8-4fe6-895c-1ada0839da44'	System	07 Jan 2021 16:34:04
User entered 'Yes (Y)'	System	07 Jan 2021 16:34:04

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-07T10:33:01', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '566d7ff9-84f8-4fe6-895c-1ada0839da44'	System	07 Jan 2021 16:34:04
User entered 'No (N)'	System	07 Jan 2021 16:34:04

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-07T10:33:07', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '566d7ff9-84f8-4fe6-895c-1ada0839da44'	System	07 Jan 2021 16:34:04
User entered 'No (N)'	System	07 Jan 2021 16:34:04

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-07T10:33:31', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '566d7ff9-84f8-4fe6-895c-1ada0839da44' User entered 'Yes (Y)'	System	07 Jan 2021 16:34:04
	System	07 Jan 2021 16:34:04

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Please 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-07T10:33:46', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '566d7ff9-84f8-4fe6-895c-1ada0839da44'	System	07 Jan 2021 16:34:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Jan 2021 16:34:04

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-07T10:33:51', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '566d7ff9-84f8-4fe6-895c-1ada0839da44' User entered '07 Jan 2021 10:33:51'	System	07 Jan 2021 16:34:04
	System	07 Jan 2021 16:34:04

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-10T08:42:56', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '78484654-5474-4fbe-852a-1092a4b8bfe7'	System	10 Jan 2021 14:43:11
User entered 'No (N)'	System	10 Jan 2021 14:43:11

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-10T08:43:05', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '78484654-5474-4fbe-852a-1092a4b8bfe7'	System	10 Jan 2021 14:43:11
User entered 'No (N)'	System	10 Jan 2021 14:43:11

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-10T08:43:08', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '78484654-5474-4fbe-852a-1092a4b8bfe7' User entered '10 Jan 2021 08:43:08'	System	10 Jan 2021 14:43:11
	System	10 Jan 2021 14:43:11

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-17T06:18:27', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bda04a76-a83a-4551-98d5-b5b393b07f4b' User entered 'No (N)'	System	17 Jan 2021 12:18:46
	System	17 Jan 2021 12:18:46



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-17T06:18:39', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bda04a76-a83a-4551-98d5-b5b393b07f4b' User entered 'No (N)'	System	17 Jan 2021 12:18:46
	System	17 Jan 2021 12:18:46

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-17T06:18:43', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bda04a76-a83a-4551-98d5-b5b393b07f4b' User entered '17 Jan 2021 06:18:43'	System	17 Jan 2021 12:18:46
	System	17 Jan 2021 12:18:46

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-24T05:41:59', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '26269e96-4d8f-4d06-abba-fc7340146c78' User entered 'No (N)'	System	27 Jan 2021 16:26:50
	System	27 Jan 2021 16:26:50

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-24T05:42:06', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '26269e96-4d8f-4d06-abba-fc7340146c78' User entered 'No (N)'	System	27 Jan 2021 16:26:50
	System	27 Jan 2021 16:26:50

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-24T05:42:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '26269e96-4d8f-4d06-abba-fc7340146c78' User entered '24 Jan 2021 05:42:11'	System	27 Jan 2021 16:26:50
	System	27 Jan 2021 16:26:50



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-31T07:18:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0f888a39-1f5d-4dfd-aae7-fa7246e04ae3'	System	31 Jan 2021 13:19:15
User entered 'No (N)'	System	31 Jan 2021 13:19:15

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-31T07:19:01', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0f888a39-1f5d-4dfd-aae7-fa7246e04ae3' User entered 'Yes (Y)'	System	31 Jan 2021 13:19:15
	System	31 Jan 2021 13:19:15

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Please 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-31T07:18:18', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0f888a39-1f5d-4dfd-aae7-fa7246e04ae3'	System	31 Jan 2021 13:19:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 13:19:15

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-01-31T07:19:04', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0f888a39-1f5d-4dfd-aae7-fa7246e04ae3' User entered '31 Jan 2021 07:19:04'	System	31 Jan 2021 13:19:15
	System	31 Jan 2021 13:19:15

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:41:33

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-07T07:06:09', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e4276523-d532-4d0c-b87f-6af29a1a7968' User entered 'No (N)'	System	07 Feb 2021 13:06:22
	System	07 Feb 2021 13:06:22

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-07T07:06:16', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e4276523-d532-4d0c-b87f-6af29a1a7968' User entered 'No (N)'	System	07 Feb 2021 13:06:22

**US3442060**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-07T07:06:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e4276523-d532-4d0c-b87f-6af29a1a7968' User entered '07 Feb 2021 07:06:20'	System	07 Feb 2021 13:06:22
	System	07 Feb 2021 13:06:22

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-14T03:38:06', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd69d9091-52e3-445d-908c-e5d958ad2d9c' User entered 'Yes (Y)'	System	14 Feb 2021 09:41:22
	System	14 Feb 2021 09:41:22

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-14T03:38:13', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd69d9091-52e3-445d-908c-e5d958ad2d9c'	System	14 Feb 2021 09:41:22
User entered 'No (N)'	System	14 Feb 2021 09:41:22

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-14T03:38:22', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd69d9091-52e3-445d-908c-e5d958ad2d9c'	System	14 Feb 2021 09:41:22
User entered 'No (N)'	System	14 Feb 2021 09:41:22

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-14T03:41:11', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd69d9091-52e3-445d-908c-e5d958ad2d9c'	System	14 Feb 2021 09:41:22
User entered 'No (N)'	System	14 Feb 2021 09:41:22

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-14T03:41:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd69d9091-52e3-445d-908c-e5d958ad2d9c' User entered '14 Feb 2021 03:41:20'	System	14 Feb 2021 09:41:22

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-21T02:07:20', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bcf3e00e-1730-4090-8e57-f73ed0c088d9'	System	01 Mar 2021 21:51:59
User entered 'No (N)'	System	01 Mar 2021 21:51:59

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-21T02:07:30', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bcf3e00e-1730-4090-8e57-f73ed0c088d9'	System	01 Mar 2021 21:51:59
User entered 'No (N)'	System	01 Mar 2021 21:51:59

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-02-21T02:07:36', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'bcf3e00e-1730-4090-8e57-f73ed0c088d9' User entered '21 Feb 2021 02:07:36'	System	01 Mar 2021 21:51:59
	System	01 Mar 2021 21:51:59

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:41:33

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-01T15:52:06-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e9604f5-5981-4f21-a530-42b160b437fb' User entered 'No (N)'	System	01 Mar 2021 21:52:20
	System	01 Mar 2021 21:52:20

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-01T15:52:10-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e9604f5-5981-4f21-a530-42b160b437fb' User entered 'No (N)'	System	01 Mar 2021 21:52:20
	System	01 Mar 2021 21:52:20



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-01T15:52:14-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '4e9604f5-5981-4f21-a530-42b160b437fb' User entered '01 Mar 2021 21:52:14'	System	01 Mar 2021 21:52:20
	System	01 Mar 2021 21:52:20

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-07T07:22:30-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e33748e-56a9-4963-9227-6362839076b9'	System	07 Mar 2021 13:22:43
User entered 'No (N)'	System	07 Mar 2021 13:22:43

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-07T07:22:37-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e33748e-56a9-4963-9227-6362839076b9'	System	07 Mar 2021 13:22:43
User entered 'No (N)'	System	07 Mar 2021 13:22:43

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-07T07:22:41-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9e33748e-56a9-4963-9227-6362839076b9' User entered '07 Mar 2021 07:22:41'	System	07 Mar 2021 13:22:43
	System	07 Mar 2021 13:22:43

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-14T18:50:12-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '95f90d4b-357c-448f-a7d6-e0936ed53a95'	System	14 Mar 2021 23:50:23
User entered 'No (N)'	System	14 Mar 2021 23:50:23

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-14T18:50:16-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '95f90d4b-357c-448f-a7d6-e0936ed53a95'	System	14 Mar 2021 23:50:23
User entered 'No (N)'	System	14 Mar 2021 23:50:23

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-14T18:50:20-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '95f90d4b-357c-448f-a7d6-e0936ed53a95'	System	14 Mar 2021 23:50:23
User entered '14 Mar 2021 18:50:20'	System	14 Mar 2021 23:50:23

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-21T07:46:21-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0e79c594-dae4-4498-a6a7-953f88780777'	System	21 Mar 2021 12:46:31
User entered 'No (N)'	System	21 Mar 2021 12:46:31

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-21T07:46:24-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0e79c594-dae4-4498-a6a7-953f88780777'	System	21 Mar 2021 12:46:31
User entered 'No (N)'	System	21 Mar 2021 12:46:31

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-21T07:46:28-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '0e79c594-dae4-4498-a6a7-953f88780777' User entered '21 Mar 2021 07:46:28'	System	21 Mar 2021 12:46:31
	System	21 Mar 2021 12:46:31

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:41:33

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-29T07:10:07-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '03cbfecb-98f9-4591-a44f-1ff9531a862e' User entered 'No (N)'	System	29 Mar 2021 12:10:19
	System	29 Mar 2021 12:10:19

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-29T07:10:12-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '03cbfecb-98f9-4591-a44f-1ff9531a862e' User entered 'No (N)'	System	29 Mar 2021 12:10:19
	System	29 Mar 2021 12:10:19



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-29T07:10:17-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '03cbfecb-98f9-4591-a44f-1ff9531a862e' User entered '29 Mar 2021 07:10:17'	System	29 Mar 2021 12:10:19
	System	29 Mar 2021 12:10:19

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-04T06:05:56-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '165eec51-cf28-4cc7-b2b3-d097510779c1' User entered 'No (N)'	System	04 Apr 2021 11:06:07
	System	04 Apr 2021 11:06:07

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-04T06:06:01-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '165eec51-cf28-4cc7-b2b3-d097510779c1' User entered 'No (N)'	System	04 Apr 2021 11:06:07

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-04T06:06:05-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '165eec51-cf28-4cc7-b2b3-d097510779c1' User entered '04 Apr 2021 06:06:05'	System	04 Apr 2021 11:06:07
	System	04 Apr 2021 11:06:07

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-13T12:49:33-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9ab5853d-1083-440b-ad4d-7c39505cdc76'	System	13 Apr 2021 17:49:43
User entered 'No (N)'	System	13 Apr 2021 17:49:43

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-13T12:49:36-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9ab5853d-1083-440b-ad4d-7c39505cdc76'	System	13 Apr 2021 17:49:43
User entered 'No (N)'	System	13 Apr 2021 17:49:43

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-13T12:49:40-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: '9ab5853d-1083-440b-ad4d-7c39505cdc76'	System	13 Apr 2021 17:49:43
User entered '13 Apr 2021 12:49:40'	System	13 Apr 2021 17:49:43

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-18T08:03:10-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e4b1d3e9-a6e1-4e31-af93-8c4423ff7741' User entered 'No (N)'	System	18 Apr 2021 13:03:19
	System	18 Apr 2021 13:03:19

US3442060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:02

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-18T08:03:12-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e4b1d3e9-a6e1-4e31-af93-8c4423ff7741' User entered 'No (N)'	System	18 Apr 2021 13:03:19

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-18T08:03:15-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'e4b1d3e9-a6e1-4e31-af93-8c4423ff7741'	System	18 Apr 2021 13:03:19
User entered '18 Apr 2021 08:03:15'	System	18 Apr 2021 13:03:19

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-25T12:54:31-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd8436c76-f227-46b5-959a-e43b6e815ea8'	System	25 Apr 2021 17:54:41
User entered 'No (N)'	System	25 Apr 2021 17:54:41

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

Have you been exposed to someone with 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 (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-25T12:54:35-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd8436c76-f227-46b5-959a-e43b6e815ea8'	System	25 Apr 2021 17:54:41
User entered 'No (N)'	System	25 Apr 2021 17:54:41



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-04-25T12:54:38-05:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'd8436c76-f227-46b5-959a-e43b6e815ea8'	System	25 Apr 2021 17:54:41
User entered '25 Apr 2021 12:54:38'	System	25 Apr 2021 17:54:41

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:41:33



**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:41:33

**US3442060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:40:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:33
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:41:33

US3442060

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:40:02**

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-01T15:52:25-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'ab07442a-a2b8-4294-955a-3db9db141365'	System	01 Mar 2021 21:52:40
User entered 'No (N)'	System	01 Mar 2021 21:52:40

US3442060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (319CFD0C-0703-4FEA-B60A-EE098846640C)', Time: '2021-03-01T15:52:31-06:00', User OID: 'PatientReportedOutcome (US3442060)', ODM File OID: 'ab07442a-a2b8-4294-955a-3db9db141365'	System	01 Mar 2021 21:52:40
User entered '01 Mar 2021 21:52:31'	System	01 Mar 2021 21:52:40

US3442060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Nov 2020 19:05:16



US3442060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '13 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Nov 2020 19:05:16

US3442060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Nov 2020 19:05:16

US3442060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Nov 2020 19:05:16

US3442060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Nov 2020 19:05:24

US3442060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:24:28
User entered '1'	System	13 Nov 2020 19:05:24

US3442060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 23:39:41

US3442060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '7 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 23:39:41

US3442060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 23:39:41



US3442060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 23:39:41

US3442060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 23:39:49

**US3442060**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:40:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User entered 'I'	System	07 Dec 2020 23:39:49

US3442060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:18:42

US3442060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '19 Jan 2021' reason for change: Data Entry Error	(b) (4)	21 Jan 2021 01:19:20
User entered '18 Jan 2021'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:18:42

US3442060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:18:42

US3442060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:18:42

US3442060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:18:53



**US3442060**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:40:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User entered '1'	System	21 Jan 2021 01:18:53

US3442060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)' reason for change: New Information	Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:38:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 08:08:17
Query 'Data is required. Please complete.' answered with 'safety call not completed yet. data entry error' (Site from System).		20 Feb 2021 20:51:09
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 20:51:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:51:05
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 20:41:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 20:41:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:41:07
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 20:39:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:39:53
User entered 'Yes (Y)'		20 Feb 2021 20:38:20

US3442060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '20 Feb 2021' reason for change: New Information	(b) (4)	22 Feb 2021 18:38:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:51:05
User entered '19 Feb 2021' reason for change: Data Entry Error		20 Feb 2021 20:41:07
User entered empty; reason for change Data Entry Error		20 Feb 2021 20:39:53
User entered '19 Feb 2021'		20 Feb 2021 20:38:20

US3442060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4)	22 Feb 2021 18:38:52
User entered empty; reason for change Data Entry Error	Oluwatosin Akingbala (b) (4)	20 Feb 2021 20:51:05
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:41:07
User entered empty; reason for change Data Entry Error		20 Feb 2021 20:39:53
User entered 'Contact Made (CONTACT MADE)'		20 Feb 2021 20:38:20

US3442060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 20:38:20

US3442060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	22 Feb 2021 18:39:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 08:08:20
Query 'Data is required. Please complete.' answered with 'safety call not completed yet. data entry error' (Site from System).		20 Feb 2021 20:50:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 20:50:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:50:30
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 20:41:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 20:41:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:41:12
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 20:40:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 20:40:01
User entered 'Yes (Y)'		20 Feb 2021 20:38:25

US3442060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:39
User entered '1'	System	22 Feb 2021 18:39:13
User entered empty.	System	20 Feb 2021 20:50:30
User entered '1'	System	20 Feb 2021 20:41:12
User entered empty.	System	20 Feb 2021 20:40:01
User entered '1'	System	20 Feb 2021 20:38:25

US3442060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:42:45



US3442060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '9 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:42:45

US3442060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:42:45

US3442060

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User entered 'VISIT4'	System	10 Mar 2021 01:42:45

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User entered empty.	System	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20



US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User entered empty.	System	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:19:06
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User entered empty.	System	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:19:06
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User entered empty.	System	30 Mar 2021 18:16:20



US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User entered empty.	System	30 Mar 2021 18:16:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29

US3442060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29

US3442060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:43:01

US3442060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:29
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:43:01

US3442060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:43:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' answered with 'Confirmed visit 4 is correct. Unscheduled kit was used as site did not have visit 4 kits.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:28:25
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	22 Mar 2021 18:22:38
User entered '9 Mar 2021'	William Seger (b) (4) (b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 08:35:36 18 Mar 2021 21:32:00 10 Mar 2021 01:43:20



US3442060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '14:49'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:43:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered '9 Mar 2021 14:49'	System	10 Mar 2021 01:43:20

US3442060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	10 Mar 2021 01:43:32

US3442060

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:26
User entered 'I'	System	10 Mar 2021 01:43:32

**US3442060**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:40:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Apr 2021 21:21:43

US3442060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
User entered '16 Apr 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Apr 2021 21:21:43

US3442060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Apr 2021 21:21:43

US3442060

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Apr 2021 21:21:43



US3442060

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Apr 2021 21:22:29

**US3442060**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:40:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 21:22:29

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:50:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:50:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[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 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:50:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 17:50:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:39

**US3442060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:40:02**

[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 17:06:41
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:15:17



US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:39

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:15:17

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:39

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:39

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 02:58:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	07 Jan 2021 17:51:39

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 02:58:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	07 Jan 2021 17:51:39

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:39

**US3442060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:40:02**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User entered empty.	System	07 Jan 2021 17:51:39



**US3442060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:40:02**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User entered empty.	System	07 Jan 2021 17:51:39

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '10:44'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:51:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User entered '7 Jan 2021 10:44'	System	07 Jan 2021 17:51:59

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:52:14

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:52:14

US3442060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '10:41'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:52:14



**US3442060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:40:02**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:41
User entered '7 Jan 2021 10:41'	System	07 Jan 2021 17:52:14

US3442060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:40:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:44
DataPoint Verified.		06 Apr 2021 15:54:44
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Oluwatosin Akingbala	21 Jan 2021 01:20:05
	(b) (4)	
User entered 'No (N)'	Melody Dufrene (b) (4)	02 Sep 2020 22:58:49
	(b) (4)	

US3442060

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Retinopathy hypertensive, LLT: Hypertensive retinopathy - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 01:11:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 01:11:12
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
Data point term sent to Coder	System	23 Feb 2021 02:18:27
Coding entries removed.	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:17:47
User entered 'HYPERTENSIVE RETINOPATHY (L)' reason for change: New Information	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:17:47
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Retinopathy hypertensive, LLT: Hypertensive retinopathy - version MedDRA\23.0.	Coder Import (b) (4)	23 Feb 2021 02:16:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Feb 2021 02:16:55
Data point term sent to Coder	System	23 Feb 2021 02:16:26
Coding entries removed.	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:15:38
User entered 'hypertensive retinopathy' reason for change: New Information	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:15:38
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Ocular discomfort, LLT: Sensation of pressure in eye - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 12:05:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 12:05:07
Data point term sent to Coder	System	25 Jan 2021 21:55:23
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 21:54:55
User entered 'EYE PRESSURE (LEFT)' reason for change: Data Entry Error		25 Jan 2021 21:54:55
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Ocular discomfort, LLT: Sensation of pressure in eye - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 10:58:23

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 10:58:23
Data point term sent to Coder	(b) (4) System	21 Jan 2021 01:27:46
User entered 'eye pressure left'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
	(b) (4)	
User entered '14 Dec 2020' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:15:38
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:54:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Jan 2021 01:30:53
User entered '30 Dec 2020' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:30:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Jan 2021 01:27:02
User entered 'UN Dec 2020' (non-conformant).	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02



**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02



US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02



US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '1'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02



US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 01:27:02

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 01:27:02

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:00:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:00:53
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:56:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:56:57
Data point term sent to Coder	System	25 Jan 2021 21:56:24
User entered 'worsening of blood pressure'	(b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00



US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 21:56:00



US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	25 Jan 2021 21:56:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:56:17
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Jan 2021 21:56:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00



US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (D) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00



**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
	(b) (4)	
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 21:56:17
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Jan 2021 21:56:17
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 21:56:00
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 21:56:17
User entered '1'	System	25 Jan 2021 21:56:00

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Jan 2021 21:56:00

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	06 Apr 2021 15:55:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:31
User entered		02 Mar 2021 16:51:20
'USA-US017-2021-mRNA-1273-P301000009'		
User entered 'New'		02 Mar 2021 16:51:20



US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 22:21:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 22:21:57
Data point term sent to Coder	System	01 Mar 2021 22:21:37
User entered 'Worsening of Left knee Osteoarthritis'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:05
User entered 'Yes (Y)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:06
User entered 'No (N)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:09
User entered 'No (N)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:10
User entered '18 Nov 2020'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:57:12
User entered empty.	Alma Guel (b) (4)	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:14
User entered 'No (N)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35



US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:15
User entered '11 Feb 2021'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:17
User entered empty.	Alma Guel (b) (4)	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:30
User entered 'Yes (Y)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:33
User entered '0'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:34
User entered '0'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:36
User entered 'I'	Alma Guel (b) (4)	01 Mar 2021 22:21:35



US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:57:41
User entered '11 Feb 2021'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:57:45
User entered '13 Feb 2021'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:57:49
User entered 'No (N)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:21
User entered empty.	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:06:23
User entered '0'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:24
User entered '0'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:25
User entered '0'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:27
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:28
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:30
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:06:31
User entered '0'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:06:32
User closed query 'Per DM CLR: Please review if a Conmed should be added as Other Action Taken as there is a CM recorded that matches this AE indication. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		24 Mar 2021 07:27:20
Query 'Per DM CLR: Please review if a Conmed should be added as Other Action Taken as there is a CM recorded that matches this AE indication. Update as appropriate. Otherwise, provide clarification.' answered with 'updated.' (Site from DM).	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:04:32
User entered '1' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:03:03
User opened query 'Per DM CLR: Please review if a Conmed should be added as Other Action Taken as there is a CM recorded that matches this AE indication. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 18:32:21
User entered '0'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:06:34
User entered 'I'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:06:38
User entered empty.	Alma Guel (b) (4)	01 Mar 2021 22:21:35

US3442060

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:06:41
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		24 Mar 2021 14:20:18
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 14:20:15
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records obtained and sent as requested. Thank you' (Site from Safety).	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:10:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Per Lead CRC, COVID-19 testing not performed' (Site from Safety).	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:04:21
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:22:58



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:40:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:22:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:22:26
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:22:18
User entered 'Subject informed that they were hospitalized on 11Feb2021-13Feb2021 due to left knee replacement surgery.'	Alma Guel (b) (4)	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 22:21:35

**US3442060**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 22:21:35

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:40:02

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:44
Query 'Per medical records, subject is taking cinnamon supplement 500 MG orally daily. Please consult with subject to obtain start and stop dates to update the logline in source and EDC. ' canceled (Site from CRA).		06 Apr 2021 21:53:19
User opened query 'Per medical records, subject is taking cinnamon supplement 500 MG orally daily. Please consult with subject to obtain start and stop dates to update the logline in source and EDC. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:43:14
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:55:13
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:25:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:31
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 20:30:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:30:24
Data point term sent to Coder	System	21 Aug 2020 20:29:28
User entered 'losartan'	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'hypertension'	(b) (4), (b) (6)	21 Aug 2020 20:28:52



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
Signature has been broken.	(b) (4)	
DataPoint Verified.	Alma Guel (b) (4)	16 Apr 2021 17:29:00
	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '50'	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:28:52



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:40:25
User closed query 'Per source the stop date is un-Dec-2020 please change the response.' (Site from CRA).		12 Apr 2021 00:40:20
Query 'Per source the stop date is un-Dec-2020 please change the response.' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	07 Apr 2021 19:28:24
Signature has been broken.	Alma Guel (b) (4)	07 Apr 2021 19:27:57
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	07 Apr 2021 19:27:57
User opened query 'Per source the stop date is un-Dec-2020 please change the response.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:32:18
DataPoint Un-verified.		06 Apr 2021 16:31:54
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:40:27
DataPoint Un-verified.	Alma Guel (b) (4)	07 Apr 2021 19:27:57
Signature has been broken.	Alma Guel (b) (4)	07 Apr 2021 19:27:57
User entered 'un Dec 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	07 Apr 2021 19:27:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:28:52

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
User entered '1'	System	21 Aug 2020 20:28:52

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
User entered '1'	System	21 Aug 2020 20:28:52

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:21:48
User entered '804 (804)'	System	21 Aug 2020 20:28:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:32:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:32:26
Data point term sent to Coder	System	21 Aug 2020 20:31:37
User entered 'amlodipine besylate'	(b) (4), (b) (6)	21 Aug 2020 20:30:51



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'hypertension'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '5'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 20:30:51



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:30:51

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:30:51

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:30:51



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 20:30:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:33:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:33:27
Data point term sent to Coder	System	21 Aug 2020 20:32:40
User entered 'simvastatin'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'high cholesterol'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '20'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 20:32:23



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:32:23



**US3442060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:32:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:32:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 20:32:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 10:54:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:54:32
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Nov 2020 22:12:30 05 Nov 2020 22:12:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:11:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:11:27
Data point term sent to Coder Data point term sent to Coder Coding entries removed.	System System (b) (4), (b) (6)	05 Oct 2020 23:10:06 05 Oct 2020 22:49:48 05 Oct 2020 22:49:14

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:34:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:34:29
Data point term sent to Coder	System	21 Aug 2020 20:33:42
User entered 'meloxicam'	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:26:56
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'recorded in med history' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 22:12:53
User entered 'OSTEOARTHRITIS: left knee and neck' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 22:12:27
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).		04 Nov 2020 13:41:59
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 11:35:33
User entered 'osteoARTHRITIS' reason for change: New Information	(b) (4), (b) (6)	05 Oct 2020 23:09:23
Query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'done' (Site from DM).		05 Oct 2020 22:49:21
User entered 'ARTHRITIS: knee and neck' reason for change: New Information	(b) (4), (b) (6)	05 Oct 2020 22:49:14

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:54:41
User entered 'arthritis'	(b) (4), (b) (6)	21 Aug 2020 20:33:23



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '15'	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 22:52:49
User entered 'once daily (QD)'		21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un Feb 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:33:23



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:53:50
User closed query 'Per medical records, PCP advised the subject to stop taking this medication. Please check with the subject and update the field as applicable' (Site from CRA).		06 Apr 2021 21:53:48
Query 'Per medical records, PCP advised the subject to stop taking this medication. Please check with the subject and update the field as applicable' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:16:17
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:15:55
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:15:55
User opened query 'Per medical records, PCP advised the subject to stop taking this medication. Please check with the subject and update the field as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:33:34
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:33:00
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:52
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 21:15:55
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:15:55
User entered '04 Feb 2021' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:15:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:33:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
User entered empty.	System	05 Oct 2020 22:52:49
User entered '1'	System	21 Aug 2020 20:33:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
User entered empty.	System	05 Oct 2020 22:52:49
User entered '1'	System	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:22
User entered empty.	System	05 Oct 2020 22:52:49
User entered '804 (804)'	System	21 Aug 2020 20:33:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:44:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 20:44:28
Data point term sent to Coder	System	21 Aug 2020 20:35:47
Data point term sent to Coder	System	21 Aug 2020 20:34:46
User entered 'alendronate sodium'	(b) (4), (b) (6)	21 Aug 2020 20:34:44



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
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	21 Aug 2020 20:35:06
User entered 'low bone density' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 20:35:06
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 20:34:44
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '70'	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
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), (b) (6)	08 Dec 2020 06:28:46
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 'correct as entered' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 22:17:31
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).		04 Nov 2020 13:42:28
User entered 'once daily (QD)'		21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 20:34:44



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un Aug 2019'	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 20:34:44

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:34:44

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:34:44



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 20:34:44

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:53:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:53:21
Data point term sent to Coder	System	05 Oct 2020 22:52:50
User entered 'vitamin d3'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	06 Apr 2021 21:55:35
User closed query 'Per medical records, subject is taking 25mcg. please refer to medical records and or subject to receive confirmation and update the field as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 21:55:33
Query 'Per medical records, subject is taking 25mcg. please refer to medical records and or subject to receive confirmation and update the field as applicable' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:16:42
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:16:35
User entered '25' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:16:35
User opened query 'Per medical records, subject is taking 25mcg. please refer to medical records and or subject to receive confirmation and update the field as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:34:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:33:58
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '125'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'ug (ug)'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 22:52:23



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:52:23



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:52:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:52:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 22:52:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
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: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:54:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:54:28
Data point term sent to Coder	System	05 Oct 2020 22:53:54
User entered 'baby aspirin'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'cardiac prophylaxis'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '81'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 22:53:39



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:56:34
User closed query 'Per medical records, PCP advised to discontinue the medication. Please check with the subject if this is an on-going med and update the field as applicable' (Site from CRA).		06 Apr 2021 21:56:32
Query 'Per medical records, PCP advised to discontinue the medication. Please check with the subject if this is an on-going med and update the field as applicable' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:15:24
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:15:05
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:15:05
User opened query 'Per medical records, PCP advised to discontinue the medication. Please check with the subject if this is an on-going med and update the field as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:36:31
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:35:04
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 22:53:39



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:56:35
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 21:15:05
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:15:05
User entered '04 Feb 2021' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
User entered '1'	System	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
User entered '1'	System	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:32
User entered '804 (804)'	System	05 Oct 2020 22:53:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:57:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:57:25
Data point term sent to Coder	System	05 Oct 2020 22:55:55
User entered 'iron'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 18:46:35
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:13:53
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:13:43
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).		03 Nov 2020 15:05:12
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 22:55:03



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '65'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 22:55:03



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:55:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:55:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:55:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 22:55:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 08:09:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 08:09:27
Data point term sent to Coder	System	05 Oct 2020 22:55:55
User entered 'magnesium'	(b) (4), (b) (6)	05 Oct 2020 22:55:41



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:43:58
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:14:20
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:14:02
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).		03 Nov 2020 15:06:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '250'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 22:55:41



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

**US3442060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:40:02**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:55:41

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:55:41

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:55:41



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 22:55:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:57:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:57:25
Data point term sent to Coder	System	05 Oct 2020 22:56:56
User entered 'calcium'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:44:54
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:14:30
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:14:25
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.		03 Nov 2020 15:05:25
' (Site from DM).		
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:56:59
User closed query 'Per medical records, subject is taking 650 mg. please change the response as applicable' (Site from CRA).		06 Apr 2021 21:56:58
Query 'Per medical records, subject is taking 650 mg. Alma Guel please change the response as applicable' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:08:43
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:08:35
User entered '650' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:08:35
User opened query 'Per medical records, subject is taking 650 mg. please change the response as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:37:52
DataPoint Un-verified.		06 Apr 2021 16:37:24
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '600'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 22:56:23



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:56:23



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:56:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:56:23

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 22:56:23

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:58:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 22:58:26
Data point term sent to Coder	System	05 Oct 2020 22:57:57
User entered 'multivitamin 50+'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:46:20
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:14:42
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:14:37
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).		03 Nov 2020 15:05:35
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	05 Oct 2020 22:57:19



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 22:57:19



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 22:57:19

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:57:19

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:57:19

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 22:57:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), COMBINATIONS, PRODUCT: ASCORBIC ACID;ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 05:41:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 05:41:26
Data point term sent to Coder	System	05 Oct 2020 23:00:58
User entered 'vitamin c and zinc'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 04:46:41
' (Site from DM). Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:14:54
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:14:49
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.		03 Nov 2020 15:05:44
' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 23:00:03



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 1000/10).' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 12:33:06
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 1000/10).' answered with 'for the brand of vitamin, the dosage is 60mg of vitamin C/ 15 mg of zinc' (Site from DM).	Tisha Davis (b) (4)	08 Feb 2021 16:48:21
User entered '60/15' reason for change: Data Entry Error	(b) (4)	08 Feb 2021 16:47:38
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 1000/10).' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:18:54
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) (6)	08 Dec 2020 06:29:08
User entered '60' reason for change: Data Entry Error	John Villegas (b) (4)	07 Dec 2020 15:38:25
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 'updated' (Site from DM).	John Villegas (b) (4)	07 Dec 2020 15:38:19
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 22:30:19

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)' reason for change: Data Entry Error	John Villegas (b) (4)	07 Dec 2020 15:38:25
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:03



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

**US3442060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:40:02**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:00:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:00:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:00:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 23:00:03



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:02:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:02:27
Data point term sent to Coder	System	05 Oct 2020 23:00:58
User entered 'fish oil'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:47:12
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:15:07
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:15:02
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).		03 Nov 2020 15:05:53
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '1000'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:41



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:00:41

**US3442060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:00:41



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:00:41

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 23:00:41

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:02:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:02:27
Data point term sent to Coder	System	05 Oct 2020 23:01:59
User entered 'tumeric'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:47:35
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:15:23
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:15:15
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).		03 Nov 2020 15:06:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '500'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:12



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:12



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:01:12

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:01:12

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:01:12

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 23:01:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:02:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:02:27
Data point term sent to Coder	System	05 Oct 2020 23:02:00
User entered 'probiotic'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:47:55
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:15:40
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:15:30
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).		03 Nov 2020 15:06:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 23:01:45



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'UN UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:01:45



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:01:45

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:01:45

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:01:45

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 23:01:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:03:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 23:03:28
Data point term sent to Coder	System	05 Oct 2020 23:03:00
User entered 'glucosamine chondroitin'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:48:14
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 22:15:52
' answered with 'updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:15:47
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).		03 Nov 2020 15:06:29
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:02:37



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'nutritional supplement'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 1500/1200).' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 13:11:53
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 1500/1200).' answered with 'data updated' (Site from DM).	Tisha Davis (b) (4)	06 Feb 2021 18:12:03
User entered '1500/1200' reason for change: Data Entry Error	(b) (4)	06 Feb 2021 18:11:53
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 1500/1200).' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:19:15
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) (6)	08 Dec 2020 06:29:15
User entered '1500' reason for change: Data Entry Error	John Villegas (b) (4)	07 Dec 2020 15:39:53
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 'updated' (Site from DM).	John Villegas (b) (4)	07 Dec 2020 15:39:45
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:25:52

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)' reason for change: Data Entry Error	John Villegas (b) (4)	07 Dec 2020 15:39:53
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Oct 2020 23:02:37



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:40:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 23:02:37

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:02:37

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 23:02:37



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 23:02:37

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 4V, PRODUCTSYNONYM: FLULAVAL QUADRIVALENT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Nov 2020 05:31:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:31:15
Data point term sent to Coder	System	02 Nov 2020 20:49:06
User entered 'flulaval quad'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'influenza'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0.5'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mL (mL)'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	02 Nov 2020 20:48:39



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 20:48:39



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
User entered empty.	System	02 Nov 2020 20:48:39

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
User entered empty.	System	02 Nov 2020 20:48:39

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:44
User entered empty.	System	02 Nov 2020 20:48:39

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
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)	21 Jan 2021 01:36:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	21 Jan 2021 01:36:11
Data point term sent to Coder	System	21 Jan 2021 01:34:48
User entered 'LOSARTAN'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'HYPERTENSION'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '100'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once daily (QD)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:53:30
User entered 'UN Dec 2020'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:34:22

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 01:34:22

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 01:34:22

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 01:34:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 07:11:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 07:11:00
User closed query 'Per CDM re-query: Thank you for adding the AE of "WORSENING OF LEFT KNEE OSTEOARTHRITIS". However con med indication is not updated. Please update the CM indication on this form to reflect the worsening condition. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:57:03
Data point term sent to Coder	System	06 Mar 2021 16:19:09
Query 'Per CDM re-query: Thank you for adding the AE of "WORSENING OF LEFT KNEE OSTEOARTHRITIS". However con med indication is not updated. Please update the CM indication on this form to reflect the worsening condition. ' answered with 'data updated' (Site from DM).	Alma Guel (b) (4)	06 Mar 2021 16:18:30
Coding entries removed.	Alma Guel (b) (4)	06 Mar 2021 16:18:18
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEFT KNEE OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:14:22

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Thank you for adding the AE of "WORSENING OF LEFT KNEE OSTEOARTHRITIS". However con med indication is not updated. Please update the CM indication on this form to reflect the worsening condition. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:14:19
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEFT KNEE OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'corresponding AE recorded' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 20:30:06
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEFT KNEE OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:32:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:40:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 07:40:20
Data point term sent to Coder	System	21 Jan 2021 01:42:49
User entered 'dexamethasone'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'worsening of LEFT KNEE OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4)	
User entered 'left knee osteoarthritis'	Alma Guel (b) (4)	06 Mar 2021 16:18:18
	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
User closed query 'Per DM CLR: Please provide the actual dose in milligrams for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:46:26
Query 'Per DM CLR: Please provide the actual dose in milligrams for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:37:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User opened query 'Per DM CLR: Please provide the actual dose in milligrams for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 04:26:25
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'I'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:39:43
DataPoint Un-verified.		09 Apr 2021 18:37:40
Signature has been broken.		09 Apr 2021 18:37:40
User entered 'mg (mg)' reason for change: Data Entry Error		09 Apr 2021 18:37:40
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mL (mL)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once (ONCE)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Other (OTHER)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'intra-Articular'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '18 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '18 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
DataPoint Verified.		06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:42:45

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
User entered empty.	System	21 Jan 2021 01:42:45

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
User entered empty.	System	21 Jan 2021 01:42:45

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:53
User entered empty.	System	21 Jan 2021 01:42:45



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OCULAR VASCULAR DISORDER AGENTS, ATC: ANTINEOVASCULARISATION AGENTS, PRODUCT: BEVACIZUMAB, PRODUCTSYNONYM: AVASTIN [BEVACIZUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:23:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:23:57
Data point term sent to Coder	System	23 Feb 2021 02:23:28
Coding entries removed.	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:22:35
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OCULAR VASCULAR DISORDER AGENTS, ATC: ANTINEOVASCULARISATION AGENTS, PRODUCT: BEVACIZUMAB, PRODUCTSYNONYM: AVASTIN [BEVACIZUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jan 2021 13:36:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jan 2021 13:36:39
Data point term sent to Coder	System	25 Jan 2021 19:06:32
Data point term sent to Coder	System	25 Jan 2021 19:06:31
User closed query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	25 Jan 2021 19:06:30
Query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'updated' (Site from System).	Oluwatosin Akingbala (b) (4)	25 Jan 2021 19:06:30
User entered 'AVASTIN (Bevacizumab)' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	25 Jan 2021 19:06:09

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	21 Jan 2021 07:47:17
Data point term sent to Coder	System	21 Jan 2021 01:48:54
User entered 'avastin'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'hypertensive retinopathy (Left)' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 02:22:35
User entered 'eye pressure (left)'	Oluwatosin Akingbala	21 Jan 2021 01:48:03
	(b) (4)	

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '1.25'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:47:17
DataPoint Un-verified.	Alma Guel (b) (4)	16 Apr 2021 17:25:30
Signature has been broken.	Alma Guel (b) (4)	16 Apr 2021 17:25:30
User entered 'as needed (PRN)' reason for change:	Alma Guel (b) (4)	16 Apr 2021 17:25:30
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'once (ONCE)' reason for change: Data	(b) (4)	
Entry Error	(b) (4)	23 Feb 2021 02:22:35
User entered 'as needed (PRN)'	Oluwatosin Akingbala	21 Jan 2021 01:48:03
	(b) (4)	



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4)	21 Jan 2021 01:48:03
	Oluwatosin Akingbala	
	(b) (4)	

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 08:57:30
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'AE date corrected, same as Con Med date ' (Site from DM).	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:24:19
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 01:31:17
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:53:44
User entered 'UN Dec 2020'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:47:48
DataPoint Un-verified.	Alma Guel (b) (4)	16 Apr 2021 17:25:30
Signature has been broken.	Alma Guel (b) (4)	16 Apr 2021 17:25:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	16 Apr 2021 17:25:30
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:22:35
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:40:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 17:47:49
DataPoint Un-verified.	Alma Guel (b) (4)	16 Apr 2021 17:25:30
Signature has been broken.	Alma Guel (b) (4)	16 Apr 2021 17:25:30
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	16 Apr 2021 17:25:30
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
	(b) (4)	
User entered '14 Dec 2020' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:22:35
User entered empty.	Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 01:48:03



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:48:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:48:03

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 01:48:03

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Mar 2021 16:23:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Mar 2021 16:23:05
Data point term sent to Coder Coding entries removed.	System Alma Guel (b) (4)	06 Mar 2021 16:22:11 06 Mar 2021 16:22:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 18:50:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 18:50:03
Data point term sent to Coder User entered 'Norco'	System Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:49:03 22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Knee Pain should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 07:14:02
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Knee Pain should be recorded, and update con med indication or provide clarification.	Alma Guel (b) (4)	06 Mar 2021 16:22:09
' answered with 'data updated' (Site from DM).		
User entered 'KNEE PAIN (LEFT) Secondary to Left knee replacement' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Mar 2021 16:22:01
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Knee Pain should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:36:16
User entered 'knee pain (left)'	Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '5-325'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Oral (ORAL)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '13 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:31:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:05

**US3442060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 18:48:05

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 18:48:05

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 18:48:05

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 08:22:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:00:54
Data point term sent to Coder User entered 'meloxicam'	System Alma Guel (b) (4)	06 Apr 2021 21:18:36 06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:00:55
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:00:57
User entered 'arthritis left neck and knee'	Alma Guel (b) (4)	06 Apr 2021 21:17:51



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:00:59
User entered '15'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:00
User entered 'mg (mg)'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:40:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:01
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:03
User entered 'once daily (QD)'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:04
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:06
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:40:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:07
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:09
User entered '12 Feb 2021'	Alma Guel (b) (4)	06 Apr 2021 21:17:51



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:40:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:10
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:12
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:13
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:17:51

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:40:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:01:15
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 21:17:51

**US3442060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:17:51

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:17:51

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 21:17:51

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 21:57:13
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)	06 Apr 2021 21:19:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 21:18:35
User entered 'aspirin'	Alma Guel (b) (4)	06 Apr 2021 21:18:28



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:14
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:16
User entered 'cardiac prophylaxis'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:17
User entered '81'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:18
User entered 'mg (mg)'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:40:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:20
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:21
User entered 'once daily (QD)'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:22
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:24
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	06 Apr 2021 21:18:28



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:26
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	06 Apr 2021 21:57:37
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 21:57:31
DataPoint Verified.		06 Apr 2021 21:57:27
User entered '12 Feb 2021'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:40:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:33
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:34
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:35
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:38
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 21:18:28

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:18:28

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:18:28



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 21:18:28

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:42
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CINNAMOMUM VERUM, PRODUCTSYNONYM: CINNAMON [CINNAMOMUM VERUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:25:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:25:25
Data point term sent to Coder	System	06 Apr 2021 21:24:41
User entered 'Cinnamon'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:43
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:45
User entered 'supplement'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:46
User entered '500'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:48
User entered 'mg (mg)'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:49
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:50
User entered 'once daily (QD)'	Alma Guel (b) (4)	06 Apr 2021 21:24:12



US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:52
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:53
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:55
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:56
User entered 'un UNK 2015'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:57:58
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:58:17
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:58:19
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:40:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:58:21
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 21:24:12



US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:40:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:24:12

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:24:12

US3442060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:40:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 21:24:12

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:40:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:44
DataPoint Verified.		06 Apr 2021 21:53:14
Query 'Per medical records, during hospitalization subject had lad and radiology procedures done - Chest PA lateral, EKG interpretation and Knee, portable 2 views LT. please add these to the loglines in EDC and source as applicable. ' canceled (Site from CRA).		06 Apr 2021 21:53:12
User opened query 'Per medical records, during hospitalization subject had lad and radiology procedures done - Chest PA lateral, EKG interpretation and Knee, portable 2 views LT. please add these to the loglines in EDC and source as applicable. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:45:12
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:53:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	22 Feb 2021 18:48:33
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 22:59:07

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:00:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered '11 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:09:44

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User closed query 'Per medical records, name of the procedure is Left total knee arthroplasty. Please change the response as applicable' (Site from CRA).		06 Apr 2021 21:52:56
Query 'Per medical records, name of the procedure is Left total knee arthroplasty. Please change the response as applicable' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:07:50
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:07:45
User entered 'LEFT total knee arthoroplasty' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:07:45
User opened query 'Per medical records, name of the procedure is Left total knee arthroplasty. Please change the response as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:01:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'left knee replacement'	(b) (4)	
	Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:09:44

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered 'Medical History (MH)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:09:44

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:02

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:53:58
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 02:09:44



US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered '11 Feb 2021'	Alma Guel (b) (4)	06 Apr 2021 21:30:36

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered 'chest pa lateral'	Alma Guel (b) (4)	06 Apr 2021 21:30:36

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:30:43
User entered 'Diagnostic (DIAGNOSTIC)'	Alma Guel (b) (4)	06 Apr 2021 21:30:36

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:30:36

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered '11 Feb 2021'	Alma Guel (b) (4)	06 Apr 2021 21:31:09

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered 'EKG'	Alma Guel (b) (4)	06 Apr 2021 21:31:09

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered 'Adverse Event (AE)'	Alma Guel (b) (4)	06 Apr 2021 21:31:09

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:40:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:31:09



US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:40:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:45
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered '11 Feb 2021'	Alma Guel (b) (4)	06 Apr 2021 21:31:41

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:40:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:45
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered 'radiology - Left knee portable 2 views'	Alma Guel (b) (4)	06 Apr 2021 21:31:41

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:40:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:45
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered 'Adverse Event (AE)'	Alma Guel (b) (4)	06 Apr 2021 21:31:41

US3442060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:40:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:28:45
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:53:00
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:31:41

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:03
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'USA-US017-2021-MRNA-1273-P301000009'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:04
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Yes (Y)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:08
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20



**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:11
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Yes (Y)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:13
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:15
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:17
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'William'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:18
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Seger'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 21:56:16
User closed query '4504 boat club is the street address. please change the street number. ' (Site from CRA).		06 Apr 2021 21:56:15
Query '4504 boat club is the street address. please change the street number. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:32:35
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:32:26
User opened query '4504 boat club is the street address. please change the street number. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:30:49
Un-reviewed for Safety.	System	24 Mar 2021 14:20:49
Signature has been broken.	System	24 Mar 2021 14:20:49
User entered '4505 Boat Club Road, Suite 400A'	System	24 Mar 2021 14:20:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
	(b) (4)	
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Mar 2021 16:26:09
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Mar 2021 16:26:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered '4505 Boat Club Road, Suite 400A'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:20
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Fort Worth'	System	02 Mar 2021 16:51:20



US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:21
Reviewed for Safety.		24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Alma Guel (b) (4)	06 Mar 2021 16:26:09

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:23
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered '76135'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:24
Reviewed for Safety.		24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'US'	(b) (4) System	02 Mar 2021 16:52:06

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:20:49
User entered '1'	System	02 Mar 2021 16:52:06

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:03
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'USA-US017-2021-MRNA-1273-P301000009'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:04
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Yes (Y)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:08
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20



US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:11
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Yes (Y)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:13
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:15
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:17
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'William'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:18
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Seger'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 21:56:16
User closed query '4504 boat club is the street address. please change the street number. ' (Site from CRA).		06 Apr 2021 21:56:15
Query '4504 boat club is the street address. please change the street number. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:32:35
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:32:26
User opened query '4504 boat club is the street address. please change the street number. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:30:49
Un-reviewed for Safety.	System	24 Mar 2021 14:20:49
Signature has been broken.	System	24 Mar 2021 14:20:49
User entered '4505 Boat Club Road, Suite 400A'	System	24 Mar 2021 14:20:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Un-reviewed for Safety.	(b) (4)	
	Alma Guel (b) (4)	06 Mar 2021 16:26:09
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Mar 2021 16:26:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered '4505 Boat Club Road, Suite 400A'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:20
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Fort Worth'	System	02 Mar 2021 16:51:20



US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:21
Reviewed for Safety.		24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Alma Guel (b) (4)	06 Mar 2021 16:26:09

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:23
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered '76135'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:24
Reviewed for Safety.		24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'US'	(b) (4) System	02 Mar 2021 16:52:06

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:20:49
User entered '1'	System	02 Mar 2021 16:52:06

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:40:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:33:52
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered '02/Mar/2021 11:52'	(b) (4) System	02 Mar 2021 16:52:06

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:02

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:33:52
Reviewed for Safety.		24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 16:52:06

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:03
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'USA-US017-2021-MRNA-1273-P301000009'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:04
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Yes (Y)'	System	02 Mar 2021 16:51:20



**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:08
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:11
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Yes (Y)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:13
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:15
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'No (N)'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:17
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'William'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:18
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Sege'	System	02 Mar 2021 16:51:20



US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:56:16
User closed query '4504 boat club is the street address. please change the street number. ' (Site from CRA).		06 Apr 2021 21:56:15
Query '4504 boat club is the street address. please change the street number. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 21:32:35
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:32:26
User opened query '4504 boat club is the street address. please change the street number. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:30:49
Un-reviewed for Safety.	System	24 Mar 2021 14:20:49
Signature has been broken.	System	24 Mar 2021 14:20:49
User entered '4505 Boat Club Road, Suite 400A'	System	24 Mar 2021 14:20:49
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4) (b) (4)	18 Mar 2021 21:32:00
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Mar 2021 16:26:09
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Mar 2021 16:26:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered '4505 Boat Club Road, Suite 400A'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:20
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered 'Fort Worth'	System	02 Mar 2021 16:51:20

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:21
Reviewed for Safety.		24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered empty.	(b) (4) Alma Guel (b) (4)	06 Mar 2021 16:26:09

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:23
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:51:57
User entered '76135'	System	02 Mar 2021 16:51:20

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:07:24
Reviewed for Safety.		24 Mar 2021 14:20:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:00
User entered 'US'	(b) (4) System	02 Mar 2021 16:52:06

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:40:02**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:20:49
User entered '1'	System	02 Mar 2021 16:52:06

**US3442060**

**Folder: SAE USA-US017-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:40:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:33:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered '24/Mar/2021 09:20'	(b) (4) System	24 Mar 2021 14:20:49

US3442060

Folder: SAE USA-US017-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:02

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:33:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:06
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 14:20:49