

US3822119 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:53:40

All time stamps listed in this document are displayed in GMT

US3822119

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

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[Participant ID](#)

US3822119

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

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US3822119

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3822119

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	CROHN'S DISEASE
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	MACULAR DEGENERATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	HYPOTHYROID
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	MOOD DISORDER
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	CHRONIC DIARRHEA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	GERD
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	GERD
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	SYSTEMIC LUPUS
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Condition	HIP PAIN
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3822119

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:52 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:52
Height ( <i>xxx.x</i> )	62 in
Weight ( <i>xxx.x</i> )	145.8 lb
BMI ( <i>xxx.x</i> )	26.72293 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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 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) 12 Feb 2021 22:48:44

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Date of assessment (dd MMM yyyy) 13 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) UN UNK 1988

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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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) 12 Feb 2021 22:48:44

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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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 186109

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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:52
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	13:04 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:04
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

13 AUG 2020

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*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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 12:35

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) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	13 AUG 2020 12:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:13	13 AUG 2020 12:13
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

13 AUG 2020 13:03

PC Open Date & Time

13 AUG 2020 12:55

PC Close Date & Time

13 AUG 2020 15:25

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 14 AUG 2020 10:42

PC Open Date & Time 13 AUG 2020 16:20

PC Close Date & Time 14 AUG 2020 11:59



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 AUG 2020 10:55

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	17 AUG 2020 08:17
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	18 AUG 2020 06:40
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 19 AUG 2020 09:54

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 7

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

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

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

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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

96.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 AUG 2020 08:45

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 9

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 12:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 10

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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	22 AUG 2020 13:13
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 11

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.

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	23 AUG 2020 20:16
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 12

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.

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 13

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.

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**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

13 AUG 2020 13:04

PC Open Date & Time

13 AUG 2020 12:55

PC Close Date & Time

13 AUG 2020 15:25

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 AUG 2020 16:20

PC Close Date & Time

14 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 10:56

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 06:41

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 09:55

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 08:46

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 13:04
PC Open Date & Time	13 AUG 2020 12:55
PC Close Date & Time	13 AUG 2020 15:25

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☐
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☐
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

13 AUG 2020 16:20

PC Close Date & Time

14 AUG 2020 11:59



US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Yes ☐

PC Time stamp

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Yes ☐

PC Time stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Yes ☐

PC Time stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 06:43
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59



US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 09:56
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 08:47
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 12:07
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 13:13
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 20:16
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59



US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3822119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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*

US3822119

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3822119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:46
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:03
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3822119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:50:03

Generated On: 10 Jun 2021 09:53:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 SEP 2020

What was the treatment time? (00:00-23:59) 10:31 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 10:31

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

US3822119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	09:55 (24 HR)
Collection date and time (derived)	17 SEP 2020 09:55

US3822119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:21	17 SEP 2020 10:21
Nasopharyngeal Swab 2	No		

US3822119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 11:03

PC Open Date & Time

17 SEP 2020 10:51

PC Close Date & Time

17 SEP 2020 13:21

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 21:23

PC Open Date & Time

17 SEP 2020 14:16

PC Close Date & Time

18 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 15:05

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

19 SEP 2020 12:04

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:23

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 16:48

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

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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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 12:00

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 13:02

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 11:05

PC Open Date & Time

17 SEP 2020 10:51

PC Close Date & Time

17 SEP 2020 13:21

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:23

PC Open Date & Time

17 SEP 2020 14:16

PC Close Date & Time

18 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 15:06

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:24

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 16:49

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 13:02

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:05
PC Open Date & Time	17 SEP 2020 10:51
PC Close Date & Time	17 SEP 2020 13:21

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 21:25
PC Open Date & Time	17 SEP 2020 14:16
PC Close Date & Time	18 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 15:06
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:24
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 16:49
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:01
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 13:03
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 SEP 2020 12:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 25 SEP 2020 15:23

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 09:53:40

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

26 SEP 2020 13:33

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

---

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 09:53:40

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

27 SEP 2020 18:55

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

---

US3822119

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 12:39

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 SEP 2020 15:23

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:53:40

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 24 SEP 2020 12:39

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

---

US3822119

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 25 SEP 2020 15:23

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59



US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 12:39
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 15:24
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:53:40

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 SEP 2020 18:55
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3822119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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*

US3822119

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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*

US3822119

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

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*



US3822119

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:48:44

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

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

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:25
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	11:36 (24 HR)
Collection date and time (derived)	21 OCT 2020 11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:50:04

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**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

14 OCT 2020 09:20:48

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 12:39:08

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59



US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	29 OCT 2020 11:03:22
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 09:12:48

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 22:40:49

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 19:10:39

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 18:43:05
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 09:57:00

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 12:00:53
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 11:20:39

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59



US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 11:25:58

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 13:43:08

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 11:50:26

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 21:48:13

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 JAN 2021 22:14:45
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 21:14:30

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 FEB 2021 19:18:46
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**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

15 FEB 2021 12:59:34

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59



US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**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

21 FEB 2021 21:25:28

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 03:44:42

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 11:38:25

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 10:03:31

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**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

22 MAR 2021 15:08:43

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 05:47:52

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 17:59:53

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

12 APR 2021 20:16:23

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59



US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 18:53:29

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 257

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

---

28 APR 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 09:28:06

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 278

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 285

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 292

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 299

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59



US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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 ☐

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59



US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 348

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 369

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 390

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 418

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 425

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 439

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 453

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 495

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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 ☐

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 523

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 530

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 FEB 2022 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 544

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 APR 2022 23:59
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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 628

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 649

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 663

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 698

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 705

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 712

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 719

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 726

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59
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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 747

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 754

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 761

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

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

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3822119**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 782

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59
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**US3822119**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:53:40**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3822119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:11:03

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:11:03

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3822119

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	19 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

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) \_\_\_\_\_

US3822119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3822119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	19 MAR 2021 10:40

US3822119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 00:01:28

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 APR 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 00:01:28

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3822119**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3822119**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822119

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:53:40

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div>

**US3822119**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:53:40**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 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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US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 14:36:49

Generated On: 10 Jun 2021 09:53:40

Date of updated informed consent ( <i>dd MMM yyyy</i> )	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Height	62 in
Weight	140.2 lb
BMI (xxx.x)	25.69653

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Height	62 in
Weight	140.2 lb
BMI (xxx.x)	25.69653
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)	22 JAN 2021
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 11:21
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Height	62 in
Weight	140.2 lb
BMI (xxx.x)	25.69653
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)	22 JAN 2021
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 12:44
Temperature (xxx.x)	97.7 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 11:51 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 11:51

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

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00-23:59)	11:33 (24 HR)
Collection date and time (derived)	22 JAN 2021 11:33



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	11:40
Collection Date and Time (derived)	22 JAN 2021 11:40

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3822119

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	14:29 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:29
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 15:20
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3822119

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*



US3822119

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 14:48 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 14:48

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

US3822119

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822119

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:59:41

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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) \_\_\_\_\_

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:40

Generated On: 10 Jun 2021 09:53:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	19 MAR 2021 10:40



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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 18:50:39

Generated On: 10 Jun 2021 09:53:40

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3822119

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

AEID	USA-US126-2020-MRNA-1273-P30 1000001
Adverse event	URINARY TRACT INFECTION
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)	03 SEP 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	03 SEP 2020 08:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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)	04 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	06 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THE PATIENT WENT TO THE ER AND WAS ADMITTED FOR A URINARY TRACT INFECTION. SHE WAS GIVEN LEVOFLOXACIN 500 MG QD X 5 DAYS. SHE WAS RELEASED ON 9/6/2020.

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed:** (b) (4) 12 Mar 2021 18:50:38

**Generated On: 10 Jun 2021 09:53:40**

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

AEID

Adverse event

ALTERED MENTAL STATUS  
DUE TO SEPSIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

AEID	
Adverse event	SEPSIS
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)	04 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

AEID	
Adverse event	TOOTH PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 AUG 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)	22 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 18:50:38

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

AEID

Adverse event

CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE  
DIAGNOSIS

Was this a medically-attended AE? Yes ☐  
No ☒

Was this a Solicited Adverse Reaction? Yes ☐  
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐  
No ☒

Start date (dd MMM yyyy) 19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☒  
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☒  
Grade 2/Moderate ☐  
Grade 3/Severe ☐  
Grade 4 ☐

Is the adverse event serious? Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐  
No ☐  
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 18:50:38

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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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

AEID	
Adverse event	ASTHMA DIAGNOSIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 18:50:38

Generated On: 10 Jun 2021 09:53:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

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 (1)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	7 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	11 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX/GERD

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 (2)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication DIPHENOXYLATE-ATROPINE

Prophylaxis Yes ☐  
No ☒

Indication FREQUENT DIARRHEA

Dose per administration 2.5-0.025

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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Form: Prior/Concomitant Medication and Vaccination (4)

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication UNK

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 (4)

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Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:58:24

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Name of Medication BUDESONIDE

Prophylaxis Yes ☐  
No ☒

Indication CROHN'S

Dose per administration 3

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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

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Name of Medication PRESER VISION

Prophylaxis Yes ☒  
No ☐

Indication EYE HEALTH

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:58:24

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Name of Medication SERTRALINE

Prophylaxis Yes ☐  
No ☒

Indication UNK

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

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Name of Medication SELIFENACIN SUCCINATE

Prophylaxis Yes ☐  
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

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Name of Medication LEVOCETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (10)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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)

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Name of Medication PROBIOTIC

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☒  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

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Name of Medication B-12

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1500

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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

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Name of Medication MAGNESIUM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

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Name of Medication CALCIUM + D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1200/1000

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify MG/IU

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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication POTASSIUM

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 99

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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication VITAMIN E

Prophylaxis Yes ☒  
No ☐

Indication 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 (16)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication B6

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 (17)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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 (18)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication GLUCOSAMINE SULFATE

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 21,000

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) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication INFLUENZA

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration UNK

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 (19)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	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)		UN SEP 2019
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication POLIO

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	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)	UN	UNK 1953
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 1953		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication MMR

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	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)	UN	UNK 1953
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 1953		
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 (22)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication VARICELLA

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	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)	UN	UNK 1953
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 1953		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication TOOTH PAIN

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication ANORA INHALER

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA, COPD

Dose per administration 62.5/25

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 (25)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HIP PAIN

Dose per administration 800

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 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"/>

US3822119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:53:40

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3822119

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:53:40

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3822119

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:53:40

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

SAEID	USA-US126-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28083
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

SAEID	USA-US126-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28083
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/SEP/2020 13:37
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

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

SAEID	USA-US126-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28083
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:59
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

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

SAEID	USA-US126-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28083
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:32
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



US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

SAEID	USA-US126-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28083
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/NOV/2020 15:09
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

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

SAEID	USA-US126-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28083
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 14:51
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

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:59:41

Generated On: 10 Jun 2021 09:53:40

SAEID	USA-US126-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28083
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 19:27
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

US3822119 (Prod: Tryon Medical Partners, PLLC)

**US3822119**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:53:40**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User entered 'US3822119'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:54:28

**US3822119**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:11

**US3822119**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:54:29

US3822119

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:11



**US3822119**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'SCRN'	System	13 Aug 2020 16:43:11

US3822119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:53:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:54:30

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '73'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'YEARS'	System	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '73'	System	13 Aug 2020 16:43:38

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Female (F)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

US3822119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:53:40

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27



**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

US3822119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:53:40

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27

**US3822119**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:40**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:27



US3822119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:53:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:38

**US3822119**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:40**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'Aug 2020'	System	13 Aug 2020 16:43:38

**US3822119**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:40**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '2020'	System	13 Aug 2020 16:43:38

**US3822119**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:40**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Amendment 2 (2)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:38

**US3822119**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:40**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:38

**US3822119**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:40**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 16:43:38

US3822119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:53:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 16:43:38

**US3822119**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:40**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:38



**US3822119**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:40**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:54:29

US3822119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:53:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'I'	System	13 Aug 2020 16:43:44

**US3822119**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:53:40**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:44

**US3822119**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:53:40**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:53:21

US3822119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:55:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:55:44
Data point term sent to Coder	System	02 Sep 2020 16:54:39
User entered 'Seasonal allergies'	Krishna Shah (b) (4)	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'UN UNK 1990'	Krishna Shah (b) (4)	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:53:43



**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'Jan 1990'	System	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '1990'	System	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:53:43

**US3822119**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:53:43

US3822119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
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)	02 Sep 2020 16:58:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:58:47
Data point term sent to Coder	System	02 Sep 2020 16:57:47
User entered 'High cholesterol'	Krishna Shah (b) (4)	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:57:14



**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:14

**US3822119**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:14



US3822119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:53:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Crohn's disease, LLT: Crohn's disease - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:58:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:58:44
Data point term sent to Coder	System	02 Sep 2020 16:57:48
User entered 'Crohn's disease'	Krishna Shah (b) (4)	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'UN UNK 1990'	Krishna Shah (b) (4)	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'Jan 1990'	System	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '1990'	System	02 Sep 2020 16:57:33



**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:33

**US3822119**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:33

US3822119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Macular degeneration - version MedDRA\\23.0.	(b) (4)	02 Sep 2020 16:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:59:49
Data point term sent to Coder	(b) (4)	02 Sep 2020 16:58:49
User entered 'Macular degeneration'	System	02 Sep 2020 16:57:52
	Krishna Shah (b) (4)	
	(b) (4)	

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:57:52

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 16:57:52

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:57:52

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:57:52

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:57:52



**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:52

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:52

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:52

**US3822119**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:57:52

US3822119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 06:45:40
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	13 Oct 2020 11:48:15
' answered with 'Conmed added' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	10 Oct 2020 10:10:03
' (Site from DM).		
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:59:49
Data point term sent to Coder	System	02 Sep 2020 16:58:49
User entered 'Hypothyroid'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 16:58:21

US3822119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:53:40

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:58:21

**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 16:58:21

**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:58:21



**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:58:21

**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:58:21

**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:21

**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:21

**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:21

**US3822119**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:21

US3822119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:53:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:59:49
Data point term sent to Coder	System	02 Sep 2020 16:58:50
User entered 'Iron deficiency anemia'	Krishna Shah (b) (4)	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:58:47



**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:47

**US3822119**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:58:47



US3822119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Psychiatric disorders, HLTG: Mood disorders and disturbances NEC, HLT: Mood disorders NEC, PT: Affective disorder, LLT: Mood disorder - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:00:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:00:53
Data point term sent to Coder	System	02 Sep 2020 16:59:52
User entered 'Mood disorder'	Krishna Shah (b) (4)	02 Sep 2020 16:59:00
	(b) (4)	

US3822119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:53:40

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:59:00

**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 16:59:00

**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:59:00

**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:59:00

**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:59:00

**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:00

**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:00



**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:00

**US3822119**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:00

US3822119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Chronic diarrhea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 17:00:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:00:53
Data point term sent to Coder	System	02 Sep 2020 16:59:53
User entered 'Chronic diarrhea'	Krishna Shah (b) (4)	02 Sep 2020 16:59:49
	(b) (4)	

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:59:49

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 16:59:49

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 16:59:49

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 16:59:49

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 16:59:49



**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:49

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:49

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:49

**US3822119**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 16:59:49

US3822119

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:02:43
Data point term sent to Coder	System	02 Sep 2020 17:01:56
User entered 'GERD'	Krishna Shah (b) (4)	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:01:29



**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:01:29

**US3822119**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:01:29

US3822119

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Oct 2020 12:00:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 12:00:51
Data point term sent to Coder	System	13 Oct 2020 11:49:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Oct 2020 11:49:37
Data point term sent to Coder	System	02 Sep 2020 17:02:58
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4)	02 Sep 2020 17:02:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:01:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:01:44
Data point term sent to Coder	System	02 Sep 2020 17:00:55
User entered 'GERD'	Krishna Shah (b) (4)	02 Sep 2020 17:00:22

US3822119

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:40

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:02:14
User entered empty.	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:00:22



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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:02:14
User entered 'I'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:00:22

**US3822119**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:02:14
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:00:22

US3822119

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:02:14
User entered empty.	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:00:22

US3822119

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:02:14
User entered '0'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:00:22

US3822119

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:40

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4)	02 Sep 2020 17:02:14
User entered empty.	(b) (4) System	02 Sep 2020 17:00:22

**US3822119**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4)	02 Sep 2020 17:02:14
User entered empty.	(b) (4) System	02 Sep 2020 17:00:22

US3822119

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:40

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4)	02 Sep 2020 17:02:14
User entered empty.	(b) (4) System	02 Sep 2020 17:00:22

**US3822119**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Oct 2020 11:49:37
DataPoint inactivated with code reason code Data not required.	Krishna Shah (b) (4)	02 Sep 2020 17:02:14
User entered empty.	(b) (4) System	02 Sep 2020 17:00:22



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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:01:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:01:44
Data point term sent to Coder	System	02 Sep 2020 17:00:53
User entered 'Osteopenia'	Krishna Shah (b) (4)	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:00:38



**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:00:38

**US3822119**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	02 Sep 2020 17:00:38

US3822119

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:53:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 17:26:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 17:26:36
Data point term sent to Coder	System	22 Oct 2020 17:25:24
User entered 'Total hysterectomy'	Krishna Shah (b) (4)	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'UN UNK 1988'	Krishna Shah (b) (4)	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'UN UNK 1988'	Krishna Shah (b) (4)	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	22 Oct 2020 17:24:50



**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'Jan 1988'	System	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '1988'	System	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'Jan 1988'	System	22 Oct 2020 17:24:50

**US3822119**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '1988'	System	22 Oct 2020 17:24:50

US3822119

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Lupus erythematosus (incl subtypes), PT: Systemic lupus erythematosus, LLT: Systemic lupus erythematosus - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 21:34:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 21:34:10
Data point term sent to Coder	System	24 Nov 2020 17:17:04
User entered 'Systemic Lupus'	(b) (4), (b) (6)	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'un UNK 1987'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:12



**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'Jan 1987'	System	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '1987'	System	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	24 Nov 2020 17:16:12

**US3822119**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	24 Nov 2020 17:16:12

US3822119

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 16:18:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 16:18:45
Data point term sent to Coder	System	22 Dec 2020 16:18:19
User entered 'HYPOTHYROIDISM'	(b) (4), (b) (6)	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'UN UNK 2003'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:17:32



**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'Jan 2003'	System	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '2003'	System	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	22 Dec 2020 16:17:32

**US3822119**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	22 Dec 2020 16:17:32



US3822119

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:53:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 19:45:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 19:45:44
Data point term sent to Coder	System	23 Dec 2020 19:44:36
User entered 'overactive bladder'	Krishna Shah (b) (4)	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	23 Dec 2020 19:43:40



**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	23 Dec 2020 19:43:40

**US3822119**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	23 Dec 2020 19:43:40

US3822119

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:53:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 13:46:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 13:46:01
Data point term sent to Coder	System	27 Jan 2021 13:45:46
User entered 'Hip Pain'	(b) (4), (b) (6)	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:44:51



**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered empty.	System	27 Jan 2021 13:44:51

**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:04:43

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:04:43

**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '11:52'	Krishna Shah (b) (4)	02 Sep 2020 17:04:43

**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '13 Aug 2020 11:52'	System	02 Sep 2020 17:04:43



US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 17:06:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 17:06:37
User entered '62' in reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:06:37
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 17:04:43
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
DataPoint set to visible.	(b) (4) System	13 Aug 2020 16:43:44

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	02 Sep 2020 17:06:44
User entered '145.8' lb reason for change: Data Entry Error	System	02 Sep 2020 17:06:44
User entered '145.8' lb reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:06:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	02 Sep 2020 17:06:37
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 17:06:37
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 17:06:37
User entered '145.8' (non-conformant).	Krishna Shah (b) (4)	02 Sep 2020 17:06:37
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Sep 2020 17:04:43
User entered empty.	System	02 Sep 2020 17:04:43
DataPoint set to visible.	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
	System	13 Aug 2020 16:43:44

**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered '26.72293'	System	02 Sep 2020 17:06:44
User entered empty.	System	02 Sep 2020 17:04:43
DataPoint set to visible.	System	13 Aug 2020 16:43:44

**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'kg/m2'	System	02 Sep 2020 17:06:44
User entered empty.	System	02 Sep 2020 17:04:43
DataPoint set to visible.	System	13 Aug 2020 16:43:44

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:34
User entered '98.7' F	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
	(b) (4)	

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty; reason for change Data Entry Error	(b) (4)	
	Krishna Shah (b) (4)	22 Oct 2020 17:23:34
User entered 'Oral (Oral)'	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
	(b) (4)	

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:04:43

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:34
User entered '60'	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
	(b) (4)	



**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'bpm'	System	02 Sep 2020 17:04:43

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:34
User entered '20'	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
	(b) (4)	

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'breaths/min'	System	02 Sep 2020 17:04:43

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:34
User entered '138'	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
	(b) (4)	

**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'mmHg'	System	02 Sep 2020 17:04:43

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:34
User entered '80'	Krishna Shah (b) (4)	02 Sep 2020 17:04:43
	(b) (4)	

**US3822119**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User entered 'mmHg'	System	02 Sep 2020 17:04:43

US3822119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 19:40:56



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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 19:40:56

**US3822119**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:53:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:06:56

**US3822119**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:53:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:06:56

US3822119

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:07:27

**US3822119**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:53:40**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:27

US3822119

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:40

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 09:36:17
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	22 Oct 2020 17:24:58
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:44:19
User entered 'Surgically sterile (SURGICALLY STERILE)'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:07:27

US3822119

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:40

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:07:27

US3822119

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:40

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'un UNK 1988' reason for change:	(b) (4)	
Data Entry Error	Krishna Shah (b) (4)	22 Oct 2020 17:24:27
User entered '1 Jan 1988'	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:07:27
	(b) (4)	



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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:53:40**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:27

US3822119

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:40

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:07:27

US3822119

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:27

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55



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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

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Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:07:55



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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'I'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

**US3822119**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:53:40**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '0'	Krishna Shah (b) (4)	02 Sep 2020 17:07:55

US3822119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:40:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:07:55



**US3822119**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:57

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:57

US3822119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[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 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	13 Aug 2020 16:43:57

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'VISIT1'	System	13 Aug 2020 16:43:57

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:40

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:54:34

US3822119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:40

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:11:29
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:11:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 15:54:34
User entered '186109' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:54:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:40

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:54:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:40

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Kelly Woodell (b) (4)	13 Aug 2020 16:44:08



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:40

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Kelly Woodell (b) (4)	13 Aug 2020 16:44:08

US3822119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:40

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Kelly Woodell (b) (4)	13 Aug 2020 16:44:08

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:53:40**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Kelly Woodell (b) (4)	13 Aug 2020 16:44:08

US3822119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:40

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Kelly Woodell (b) (4)	13 Aug 2020 16:44:08

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:53:40**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:58:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:01:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:09
User entered '62' in	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:09
User entered '145.8' lb	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:09
User entered '62' in	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:09
User entered '145.8' lb	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Pre-Dose (PREDOSE)'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:09:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Sep 2020 17:08:30
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '11:52' reason for change: Data Entry Error	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '13 Aug 2020 11:52'	System	02 Sep 2020 17:09:20
User entered empty.	System	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '98.7' F reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:08:30



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '60' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'bpm'	System	02 Sep 2020 17:09:20
User entered empty.	System	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '20' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'breaths/min'	System	02 Sep 2020 17:09:20
User entered empty.	System	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '138' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	02 Sep 2020 17:09:20
User entered empty.	System	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '80' reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:09:20
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:08:30



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	02 Sep 2020 17:09:20
User entered empty.	System	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:09
User entered '62' in	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Oct 2020 17:23:09
User entered '145.8' lb	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Post-Dose (POSTDOSE)'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:08:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:10:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Sep 2020 17:08:30
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User entered empty.	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13:04' reason for change: Data Entry Error	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User entered empty.	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '13 Aug 2020 13:04'	System	02 Sep 2020 17:10:11
User entered empty.	System	02 Sep 2020 17:08:30



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '98.7' F reason for change: Data Entry Error	System	28 Sep 2020 14:22:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Krishna Shah (b) (4)	28 Sep 2020 14:22:55
User entered '98.7' (non-conformant).	(b) (4)	
User entered empty.	System	02 Sep 2020 17:10:11
	Krishna Shah (b) (4)	02 Sep 2020 17:10:11
	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '72' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User entered empty.	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'bpm'	System	02 Sep 2020 17:10:11
User entered empty.	System	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '18' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User entered empty.	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'breaths/min'	System	02 Sep 2020 17:10:11
User entered empty.	System	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
	System	16 Sep 2020 23:55:22
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:55:22
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:55:22
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 17:10:11
User entered '158' reason for change: Data Entry Error	Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User entered empty.	(b) (4)	
	Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	02 Sep 2020 17:10:11
User entered empty.	System	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '81' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:10:11
User entered empty.	(b) (4) Krishna Shah (b) (4)	02 Sep 2020 17:08:30
	(b) (4)	

US3822119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	02 Sep 2020 17:10:11
User entered empty.	System	02 Sep 2020 17:08:30

US3822119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:11:28

US3822119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:11:28

US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 16:45:02

US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 16:45:02

US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 16:45:02



US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 16:45:02

US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Kelly Woodell (b) (4)	13 Aug 2020 16:45:02

US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '12:35'	Kelly Woodell (b) (4)	13 Aug 2020 16:45:02

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:53:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '13 Aug 2020 12:35'	System	13 Aug 2020 16:45:02

US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	13 Aug 2020 16:45:02

US3822119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'ONCE'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:53:40**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 16:45:02

US3822119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:11:49



US3822119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:11:49

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '12:00'	Krishna Shah (b) (4)	02 Sep 2020 17:11:49

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '13 Aug 2020 12:00'	System	02 Sep 2020 17:11:49

US3822119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:53:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '13 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:12:05

US3822119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:53:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:12:05

US3822119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:53:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:12:05

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:40**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '12:13'	Krishna Shah (b) (4)	02 Sep 2020 17:12:05

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '13 Aug 2020 12:13'	System	02 Sep 2020 17:12:05



US3822119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:53:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:12:05

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Krishna Shah (b) (4)	02 Sep 2020 17:12:05

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:40**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:12:05

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered empty.	System	02 Sep 2020 17:12:05

US3822119

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:12:11

**US3822119**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'I'	System	02 Sep 2020 17:12:11

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:02:25', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e02454fe-f47e-4bff-83f0-539ccc303823' User entered 'Yes (Y)'	System	13 Aug 2020 17:03:16
	System	13 Aug 2020 17:03:16



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:02:39', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e02454fe-f47e-4bff-83f0-539ccc303823' User entered '98.7'	System	13 Aug 2020 17:03:16
	System	13 Aug 2020 17:03:16

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:02:47', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e02454fe-f47e-4bff-83f0-539ccc303823' User entered 'No (N)'	System	13 Aug 2020 17:03:16
	System	13 Aug 2020 17:03:16

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:03:14', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e02454fe-f47e-4bff-83f0-539ccc303823' User entered '13 Aug 2020 13:03'	System	13 Aug 2020 17:03:16
	System	13 Aug 2020 17:03:16

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 12:55'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 15:25'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-14T10:42:09', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7999a6ea-c8f9-4ddb-be8a-c3bb108fe0bc' User entered 'Yes (Y)'	System	14 Aug 2020 14:42:54
	System	14 Aug 2020 14:42:54

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-14T10:42:23', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7999a6ea-c8f9-4ddb-be8a-c3bb108fe0bc' User entered '98.7'	System	14 Aug 2020 14:42:54
	System	14 Aug 2020 14:42:54



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-14T10:42:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7999a6ea-c8f9-4ddb-be8a-c3bb108fe0bc'	System	14 Aug 2020 14:42:54
User entered 'No (N)'	System	14 Aug 2020 14:42:54

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-14T10:42:50', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7999a6ea-c8f9-4ddb-be8a-c3bb108fe0bc' User entered '14 Aug 2020 10:42'	System	14 Aug 2020 14:42:54
	System	14 Aug 2020 14:42:54

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 16:20'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 2'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 3'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:54:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9543865-73bf-4196-8b33-3abdd15a9201' User entered 'Yes (Y)'	System	16 Aug 2020 14:55:24
	System	16 Aug 2020 14:55:24

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:54:47', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9543865-73bf-4196-8b33-3abdd15a9201' User entered '97.2'	System	16 Aug 2020 14:55:24
	System	16 Aug 2020 14:55:24



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:54:54', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9543865-73bf-4196-8b33-3abdd15a9201'	System	16 Aug 2020 14:55:24
User entered 'Yes (Y)'	System	16 Aug 2020 14:55:24

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Per source medication was taken to treat tooth pain. Ae will be added and con med.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:48:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Kelly Woodell (b) (4)	10 Nov 2020 20:36:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:55:03', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9543865-73bf-4196-8b33-3abdd15a9201'	System	16 Aug 2020 14:55:24
User entered '1'	System	16 Aug 2020 14:55:24

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:55:03', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9543865-73bf-4196-8b33-3abdd15a9201' User entered '0'	System	16 Aug 2020 14:55:24
	System	16 Aug 2020 14:55:24

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:55:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9543865-73bf-4196-8b33-3abdd15a9201' User entered '16 Aug 2020 10:55'	System	16 Aug 2020 14:55:24
	System	16 Aug 2020 14:55:24

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 4'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-17T08:17:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd94ce37e-78c6-4313-b342-093f2bb1a29d' User entered 'Yes (Y)'	System	17 Aug 2020 12:17:38
	System	17 Aug 2020 12:17:38



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-17T08:17:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd94ce37e-78c6-4313-b342-093f2bb1a29d' User entered '97.7'	System	17 Aug 2020 12:17:38
	System	17 Aug 2020 12:17:38

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-17T08:17:15', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd94ce37e-78c6-4313-b342-093f2bb1a29d'	System	17 Aug 2020 12:17:38
User entered 'Yes (Y)'	System	17 Aug 2020 12:17:38

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:48:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-17T08:17:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd94ce37e-78c6-4313-b342-093f2bb1a29d' User entered '1'	Kelly Woodell (b) (4)	10 Nov 2020 20:44:53
	System	17 Aug 2020 12:17:38
	System	17 Aug 2020 12:17:38
	System	17 Aug 2020 12:17:38

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-17T08:17:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd94ce37e-78c6-4313-b342-093f2bb1a29d' User entered '0'	System	17 Aug 2020 12:17:38
	System	17 Aug 2020 12:17:38

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-17T08:17:36', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd94ce37e-78c6-4313-b342-093f2bb1a29d' User entered '17 Aug 2020 08:17'	System	17 Aug 2020 12:17:38
	System	17 Aug 2020 12:17:38

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 5'	System	13 Aug 2020 16:45:02



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:39:49', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ed66da8f-3a9c-40e6-bef5-d2739dde06e8' User entered 'Yes (Y)'	System	18 Aug 2020 10:40:39
	System	18 Aug 2020 10:40:39

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:40:01', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ed66da8f-3a9c-40e6-bef5-d2739dde06e8' User entered '97.0'	System	18 Aug 2020 10:40:39
	System	18 Aug 2020 10:40:39

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:40:06', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ed66da8f-3a9c-40e6-bef5-d2739dde06e8'	System	18 Aug 2020 10:40:39
User entered 'Yes (Y)'	System	18 Aug 2020 10:40:39

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:49:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:40:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ed66da8f-3a9c-40e6-bef5-d2739dde06e8' User entered '1'	Kelly Woodell (b) (4)	10 Nov 2020 20:45:00
	System	18 Aug 2020 10:40:39
	System	18 Aug 2020 10:40:39
	System	18 Aug 2020 10:40:39

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:40:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ed66da8f-3a9c-40e6-bef5-d2739dde06e8' User entered '0'	System	18 Aug 2020 10:40:39
	System	18 Aug 2020 10:40:39

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:40:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ed66da8f-3a9c-40e6-bef5-d2739dde06e8' User entered '18 Aug 2020 06:40'	System	18 Aug 2020 10:40:39
	System	18 Aug 2020 10:40:39

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:45:02



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 6'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:53:19', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f8841d80-3901-4a78-b01e-7ac9bfe17246' User entered 'Yes (Y)'	System	19 Aug 2020 13:54:08
	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:53:27', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f8841d80-3901-4a78-b01e-7ac9bfe17246' User entered '97.1'	System	19 Aug 2020 13:54:08
	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:53:32', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f8841d80-3901-4a78-b01e-7ac9bfe17246'	System	19 Aug 2020 13:54:08
User entered 'Yes (Y)'	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:49:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:53:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f8841d80-3901-4a78-b01e-7ac9bfe17246' User entered '1'	Kelly Woodell (b) (4)	10 Nov 2020 20:45:05
	System	19 Aug 2020 13:54:08
	System	19 Aug 2020 13:54:08
	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:53:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f8841d80-3901-4a78-b01e-7ac9bfe17246' User entered '0'	System	19 Aug 2020 13:54:08
	System	19 Aug 2020 13:54:08

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:54:05', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f8841d80-3901-4a78-b01e-7ac9bfe17246' User entered '19 Aug 2020 09:54'	System	19 Aug 2020 13:54:08
	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:45:02



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 7'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:44:50', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'af3b7165-8301-45ff-bfb3-226c88155154'	System	20 Aug 2020 12:45:32
User entered 'Yes (Y)'	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:44:59', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'af3b7165-8301-45ff-bfb3-226c88155154' User entered '96.2'	System	20 Aug 2020 12:45:32
	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:45:11', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'af3b7165-8301-45ff-bfb3-226c88155154'	System	20 Aug 2020 12:45:32
User entered 'Yes (Y)'	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:49:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:45:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'af3b7165-8301-45ff-bfb3-226c88155154'	Kelly Woodell (b) (4)	10 Nov 2020 20:45:12
User entered '1'	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:45:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'af3b7165-8301-45ff-bfb3-226c88155154'	System	20 Aug 2020 12:45:32
User entered '0'	System	20 Aug 2020 12:45:32

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:45:28', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'af3b7165-8301-45ff-bfb3-226c88155154'	System	20 Aug 2020 12:45:32
User entered '20 Aug 2020 08:45'	System	20 Aug 2020 12:45:32



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	19 Aug 2020 13:54:08
User entered 'Day 8'	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	20 Aug 2020 12:45:32
User entered 'Day 9'	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:06:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '654cd6cc-1cfd-4405-b4a8-b5eb30caf31e' User entered 'Yes (Y)'	System	21 Aug 2020 16:07:21
	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:06:55', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '654cd6cc-1cfd-4405-b4a8-b5eb30caf31e' User entered '97.2'	System	21 Aug 2020 16:07:21
	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:07:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '654cd6cc-1cfd-4405-b4a8-b5eb30caf31e' User entered 'Yes (Y)'	System	21 Aug 2020 16:07:21
	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:49:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:07:09', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '654cd6cc-1cfd-4405-b4a8-b5eb30caf31e' User entered '1'	Kelly Woodell (b) (4)	10 Nov 2020 20:45:23
	System	21 Aug 2020 16:07:21
	System	21 Aug 2020 16:07:21
	System	21 Aug 2020 16:07:21



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:07:09', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '654cd6cc-1cfd-4405-b4a8-b5eb30caf31e' User entered '0'	System	21 Aug 2020 16:07:21
	System	21 Aug 2020 16:07:21

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:07:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '654cd6cc-1cfd-4405-b4a8-b5eb30caf31e' User entered '21 Aug 2020 12:07'	System	21 Aug 2020 16:07:21
	System	21 Aug 2020 16:07:21

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	21 Aug 2020 16:07:21
User entered 'Day 10'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:13', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c1d6864e-132f-4a43-97a1-784b73541d64' User entered 'Yes (Y)'	System	22 Aug 2020 17:13:41
	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:19', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c1d6864e-132f-4a43-97a1-784b73541d64' User entered '98.0'	System	22 Aug 2020 17:13:41
	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:24', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c1d6864e-132f-4a43-97a1-784b73541d64' User entered 'Yes (Y)'	System	22 Aug 2020 17:13:41
	System	22 Aug 2020 17:13:41



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:49:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:30', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c1d6864e-132f-4a43-97a1-784b73541d64' User entered '1'	Kelly Woodell (b) (4)	10 Nov 2020 20:45:29
	System	22 Aug 2020 17:13:41
	System	22 Aug 2020 17:13:41
	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:30', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c1d6864e-132f-4a43-97a1-784b73541d64' User entered '0'	System	22 Aug 2020 17:13:41
	System	22 Aug 2020 17:13:41

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c1d6864e-132f-4a43-97a1-784b73541d64' User entered '22 Aug 2020 13:13'	System	22 Aug 2020 17:13:41
	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	21 Aug 2020 16:07:21
User entered 'Day 11'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:15:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7e345ad6-dd0b-4eb3-b1bc-42b9efdcfb0c' User entered 'Yes (Y)'	System	24 Aug 2020 00:16:13
	System	24 Aug 2020 00:16:13

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:15:54', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7e345ad6-dd0b-4eb3-b1bc-42b9efdcfb0c' User entered '97.2'	System	24 Aug 2020 00:16:13
	System	24 Aug 2020 00:16:13



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:16:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7e345ad6-dd0b-4eb3-b1bc-42b9efdcfb0c' User entered 'Yes (Y)'	System	24 Aug 2020 00:16:13
	System	24 Aug 2020 00:16:13

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:49:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:16:04', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7e345ad6-dd0b-4eb3-b1bc-42b9efdcfb0c' User entered '1'	Kelly Woodell (b) (4)	10 Nov 2020 20:45:37
	System	24 Aug 2020 00:16:13
	System	24 Aug 2020 00:16:13
	System	24 Aug 2020 00:16:13

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:16:04', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7e345ad6-dd0b-4eb3-b1bc-42b9efdcfb0c' User entered '0'	System	24 Aug 2020 00:16:13
	System	24 Aug 2020 00:16:13

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:16:09', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7e345ad6-dd0b-4eb3-b1bc-42b9efdcfb0c' User entered '23 Aug 2020 20:16'	System	24 Aug 2020 00:16:13
	System	24 Aug 2020 00:16:13

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	22 Aug 2020 17:13:41
User entered 'Day 12'	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	24 Aug 2020 00:16:13
User entered 'Day 13'	System	24 Aug 2020 00:16:13



US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:16:13

US3822119

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:16:13



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:01', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '783c6d18-587e-46b6-bb1d-2be8a4eccbcb' User entered 'None (1)'	System	13 Aug 2020 17:04:25
	System	13 Aug 2020 17:04:25

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:07', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '783c6d18-587e-46b6-bb1d-2be8a4eccbcb' User entered 'No (N)'	System	13 Aug 2020 17:04:25
	System	13 Aug 2020 17:04:25

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:13', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '783c6d18-587e-46b6-bb1d-2be8a4eccbcb' User entered 'No (N)'	System	13 Aug 2020 17:04:25
	System	13 Aug 2020 17:04:25

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '783c6d18-587e-46b6-bb1d-2be8a4eccbcb' User entered 'None (1)'	System	13 Aug 2020 17:04:25
	System	13 Aug 2020 17:04:25

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '783c6d18-587e-46b6-bb1d-2be8a4eccbcb' User entered '13 Aug 2020 13:04'	System	13 Aug 2020 17:04:25
	System	13 Aug 2020 17:04:25

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 12:55'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 15:25'	System	13 Aug 2020 16:45:02



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 16:20'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 2'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 3'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:56:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '364c722a-fc9a-45df-b0fe-26c5352affde'	System	16 Aug 2020 14:56:36
User entered 'None (1)'	System	16 Aug 2020 14:56:36

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:56:06', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '364c722a-fc9a-45df-b0fe-26c5352affde'	System	16 Aug 2020 14:56:36
User entered 'No (N)'	System	16 Aug 2020 14:56:36

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:56:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '364c722a-fc9a-45df-b0fe-26c5352affde' User entered 'No (N)'	System	16 Aug 2020 14:56:36
	System	16 Aug 2020 14:56:36



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:56:21', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '364c722a-fc9a-45df-b0fe-26c5352affde' User entered 'None (1)'	System	16 Aug 2020 14:56:36
	System	16 Aug 2020 14:56:36

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-16T10:56:32', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '364c722a-fc9a-45df-b0fe-26c5352affde' User entered '16 Aug 2020 10:56'	System	16 Aug 2020 14:56:36
	System	16 Aug 2020 14:56:36

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 4'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 5'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:41:25', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12924ed2-8c12-4d0e-bf6c-f300983d5be6'	System	18 Aug 2020 10:41:54
User entered 'None (1)'	System	18 Aug 2020 10:41:54



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:41:30', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12924ed2-8c12-4d0e-bf6c-f300983d5be6' User entered 'No (N)'	System	18 Aug 2020 10:41:54
	System	18 Aug 2020 10:41:54

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:41:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12924ed2-8c12-4d0e-bf6c-f300983d5be6' User entered 'No (N)'	System	18 Aug 2020 10:41:54
	System	18 Aug 2020 10:41:54

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:41:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12924ed2-8c12-4d0e-bf6c-f300983d5be6' User entered 'None (1)'	System	18 Aug 2020 10:41:54
	System	18 Aug 2020 10:41:54

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:41:52', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12924ed2-8c12-4d0e-bf6c-f300983d5be6' User entered '18 Aug 2020 06:41'	System	18 Aug 2020 10:41:54
	System	18 Aug 2020 10:41:54

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 6'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:55:07', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f022f7b1-fecc-4398-a14b-927ca8e5eda0'	System	19 Aug 2020 13:55:20
User entered 'None (1)'	System	19 Aug 2020 13:55:20



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:54:47', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f022f7b1-fecc-4398-a14b-927ca8e5eda0' User entered 'No (N)'	System	19 Aug 2020 13:55:20
	System	19 Aug 2020 13:55:20

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:54:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f022f7b1-fecc-4398-a14b-927ca8e5eda0' User entered 'No (N)'	System	19 Aug 2020 13:55:20
	System	19 Aug 2020 13:55:20

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:54:57', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f022f7b1-fecc-4398-a14b-927ca8e5eda0' User entered 'None (1)'	System	19 Aug 2020 13:55:20
	System	19 Aug 2020 13:55:20

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:55:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f022f7b1-fecc-4398-a14b-927ca8e5eda0' User entered '19 Aug 2020 09:55'	System	19 Aug 2020 13:55:20
	System	19 Aug 2020 13:55:20

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 7'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:45:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '354494ab-ff3a-4b7c-a756-1f2266f1054e' User entered 'None (1)'	System	20 Aug 2020 12:46:13
	System	20 Aug 2020 12:46:13



US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:45:55', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '354494ab-ff3a-4b7c-a756-1f2266f1054e' User entered 'No (N)'	System	20 Aug 2020 12:46:13
	System	20 Aug 2020 12:46:13

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:46:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '354494ab-ff3a-4b7c-a756-1f2266f1054e' User entered 'No (N)'	System	20 Aug 2020 12:46:13
	System	20 Aug 2020 12:46:13

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:46:04', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '354494ab-ff3a-4b7c-a756-1f2266f1054e' User entered 'None (1)'	System	20 Aug 2020 12:46:13
	System	20 Aug 2020 12:46:13

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:46:11', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '354494ab-ff3a-4b7c-a756-1f2266f1054e' User entered '20 Aug 2020 08:46'	System	20 Aug 2020 12:46:13
	System	20 Aug 2020 12:46:13

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:30', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27' User entered 'None (0)'	System	13 Aug 2020 17:05:01
	System	13 Aug 2020 17:05:01



**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27' User entered 'None (0)'	System	13 Aug 2020 17:05:01
	System	13 Aug 2020 17:05:01

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27' User entered 'None (0)'	System	13 Aug 2020 17:05:01
	System	13 Aug 2020 17:05:01

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:40', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27' User entered 'None (0)'	System	13 Aug 2020 17:05:01
	System	13 Aug 2020 17:05:01

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:43', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27' User entered 'None (0)'	System	13 Aug 2020 17:05:01
	System	13 Aug 2020 17:05:01

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27' User entered 'None (0)'	System	13 Aug 2020 17:05:01
	System	13 Aug 2020 17:05:01

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:54', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27'	System	13 Aug 2020 17:05:01
User entered 'No (N)'	System	13 Aug 2020 17:05:01

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-13T13:04:59', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2cce023b-6cc3-4e14-b5da-005f11a7aa27' User entered '13 Aug 2020 13:04'	System	13 Aug 2020 17:05:01
	System	13 Aug 2020 17:05:01

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 12:55'	System	13 Aug 2020 16:45:02



**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 15:25'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '13 Aug 2020 16:20'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 2'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 3'	System	13 Aug 2020 16:45:02



US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 4'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 5'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:42:07', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670'	System	18 Aug 2020 10:43:58
User entered 'None (0)'	System	18 Aug 2020 10:43:58

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:42:49', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670'	System	18 Aug 2020 10:43:58
User entered 'None (0)'	System	18 Aug 2020 10:43:58



US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:42:58', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670' User entered 'None (0)'	System	18 Aug 2020 10:43:58
	System	18 Aug 2020 10:43:58

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:43:12', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670' User entered 'None (0)'	System	18 Aug 2020 10:43:58
	System	18 Aug 2020 10:43:58

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:43:15', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670' User entered 'None (0)'	System	18 Aug 2020 10:43:58
	System	18 Aug 2020 10:43:58

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:43:18', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670' User entered 'None (0)'	System	18 Aug 2020 10:43:58
	System	18 Aug 2020 10:43:58

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:43:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670'	System	18 Aug 2020 10:43:58
User entered 'No (N)'	System	18 Aug 2020 10:43:58

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-18T06:43:56', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'cff3ce90-744b-4f5e-bc54-23e7b2c47670' User entered '18 Aug 2020 06:43'	System	18 Aug 2020 10:43:58
	System	18 Aug 2020 10:43:58

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 16:45:02



US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 6'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:55:38', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9'	System	19 Aug 2020 13:56:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Aug 2020 13:56:37

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:55:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9' User entered 'None (0)'	System	19 Aug 2020 13:56:37
	System	19 Aug 2020 13:56:37

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:55:53', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9' User entered 'None (0)'	System	19 Aug 2020 13:56:37
	System	19 Aug 2020 13:56:37

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:55:56', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9' User entered 'None (0)'	System	19 Aug 2020 13:56:37
	System	19 Aug 2020 13:56:37

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:56:01', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9' User entered 'None (0)'	System	19 Aug 2020 13:56:37
	System	19 Aug 2020 13:56:37

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:56:04', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9' User entered 'None (0)'	System	19 Aug 2020 13:56:37
	System	19 Aug 2020 13:56:37

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:56:27', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9' User entered 'No (N)'	System	19 Aug 2020 13:56:37
	System	19 Aug 2020 13:56:37



**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-19T09:56:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9fd4b9e5-2eaa-42d1-bd70-0c0c176793d9' User entered '19 Aug 2020 09:56'	System	19 Aug 2020 13:56:37
	System	19 Aug 2020 13:56:37

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 7'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:46:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered 'None (0)'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:46:43', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered 'None (0)'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:46:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered 'None (0)'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:46:56', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered 'None (0)'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30



**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:47:02', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered 'None (0)'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:47:06', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered 'None (0)'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30

US3822119

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:47:14', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered 'No (N)'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-20T08:47:25', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '128efbab-2e2c-4c9d-91de-8f462a86f4c3' User entered '20 Aug 2020 08:47'	System	20 Aug 2020 12:47:30
	System	20 Aug 2020 12:47:30

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 16:45:02

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	19 Aug 2020 13:54:08
User entered 'Day 8'	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18



US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:54:08

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:54:08

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	20 Aug 2020 12:45:32
User entered 'Day 9'	System	20 Aug 2020 12:45:32

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:07:33', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '35e7fbe6-14e1-4172-8b4c-447d00e4429f' User entered 'No (N)'	System	21 Aug 2020 16:07:52
	System	21 Aug 2020 16:07:52

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-21T12:07:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '35e7fbe6-14e1-4172-8b4c-447d00e4429f' User entered '21 Aug 2020 12:07'	System	21 Aug 2020 16:07:52
	System	21 Aug 2020 16:07:52

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 12:45:32

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 12:45:32



US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	21 Aug 2020 16:07:21
User entered 'Day 10'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:47', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '13e7b93d-2321-41b4-84ae-05d51dde01ca' User entered 'No (N)'	System	22 Aug 2020 17:13:59
	System	22 Aug 2020 17:13:59

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-22T13:13:57', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '13e7b93d-2321-41b4-84ae-05d51dde01ca' User entered '22 Aug 2020 13:13'	System	22 Aug 2020 17:13:59
	System	22 Aug 2020 17:13:59

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:07:21

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	21 Aug 2020 16:07:21
User entered 'Day 11'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:16:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ac51ef84-d9b6-488b-91dd-c9ddbc3667cb' User entered 'No (N)'	System	24 Aug 2020 00:16:40
	System	24 Aug 2020 00:16:40

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9E23FE93-5394-4659-B388-0EC1DA720E48)', Time: '2020-08-23T20:16:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ac51ef84-d9b6-488b-91dd-c9ddbc3667cb' User entered '23 Aug 2020 20:16'	System	24 Aug 2020 00:16:40
	System	24 Aug 2020 00:16:40



**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:07:21

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:07:21

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	22 Aug 2020 17:13:41
User entered 'Day 12'	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:13:41

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	24 Aug 2020 00:16:13
User entered 'Day 13'	System	24 Aug 2020 00:16:13



US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18

**US3822119**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:16:13

US3822119

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:16:13

**US3822119**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:12:41

**US3822119**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '22 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:12:41

**US3822119**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	02 Sep 2020 17:12:41

US3822119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	02 Sep 2020 17:12:41



US3822119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:12:48

**US3822119**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'I'	System	02 Sep 2020 17:12:48

**US3822119**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:13:08

**US3822119**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '28 Aug 2020'	Krishna Shah (b) (4)	02 Sep 2020 17:13:08

US3822119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	02 Sep 2020 17:13:08

US3822119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Krishna Shah (b) (4)	02 Sep 2020 17:13:08

US3822119

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Krishna Shah (b) (4)	02 Sep 2020 17:13:14

**US3822119**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'I'	System	02 Sep 2020 17:13:14



**US3822119**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	09 Sep 2020 23:40:46

US3822119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '4 Sep 2020'	Kelly Woodell (b) (4)	09 Sep 2020 23:40:46

US3822119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	09 Sep 2020 23:40:46

US3822119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	09 Sep 2020 23:40:46

US3822119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	09 Sep 2020 23:40:50

**US3822119**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'I'	System	09 Sep 2020 23:40:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	17 Sep 2020 14:39:04

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '17 Sep 2020'	Kelly Woodell (b) (4)	17 Sep 2020 14:39:04



US3822119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[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 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	17 Sep 2020 14:39:04

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'VISIT2'	System	17 Sep 2020 14:39:04

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '09:46'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '17 Sep 2020 09:46'	System	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40



US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '60'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'bpm'	System	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'breaths/min'	System	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '122'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	13 Oct 2020 11:51:40



US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '80'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '11:03'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '17 Sep 2020 11:03'	System	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40



US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '69'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'bpm'	System	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'breaths/min'	System	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '125'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	13 Oct 2020 11:51:40



US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '83'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	13 Oct 2020 11:51:40

US3822119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'No (N)'	Kelly Woodell (b) (4)	17 Sep 2020 14:41:28

US3822119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered empty.	Kelly Woodell (b) (4)	17 Sep 2020 14:41:28

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 14:41:52



US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '17 Sep 2020'	Kelly Woodell (b) (4)	17 Sep 2020 14:41:52

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:53:40**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '10:31'	Kelly Woodell (b) (4)	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '17 Sep 2020 10:31'	System	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'ONCE'	System	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 14:41:52

US3822119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 21OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 10:10:53
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 21OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'added' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:10:51
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 21OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 17:17:13
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	17 Sep 2020 14:42:44

US3822119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '17 Sep 2020'	Kelly Woodell (b) (4)	17 Sep 2020 14:42:44



US3822119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '09:55' reason for change: Data Entry Error	Kelly Woodell (b) (4)	17 Sep 2020 14:43:34
User entered '10:31'	Kelly Woodell (b) (4)	17 Sep 2020 14:42:44

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '17 Sep 2020 09:55'	System	17 Sep 2020 14:43:34
User entered '17 Sep 2020 10:31'	System	17 Sep 2020 14:42:44

US3822119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:53:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '17 Sep 2020'	Kelly Woodell (b) (4)	17 Sep 2020 14:43:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	17 Sep 2020 14:43:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	17 Sep 2020 14:43:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered '10:21'	Kelly Woodell (b) (4)	17 Sep 2020 14:43:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '17 Sep 2020 10:21'	System	17 Sep 2020 14:43:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	17 Sep 2020 14:43:50



**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'No (N)'	Kelly Woodell (b) (4)	17 Sep 2020 14:43:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:40**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	Kelly Woodell (b) (4)	17 Sep 2020 14:43:50

**US3822119**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered empty.	System	17 Sep 2020 14:43:50

US3822119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	17 Sep 2020 14:48:29

US3822119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'I'	System	17 Sep 2020 14:48:29

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:03:21', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a3fb2712-055b-4f5c-b822-8a681d58fbc1' User entered 'Yes (Y)'	System	17 Sep 2020 15:03:50
	System	17 Sep 2020 15:03:50

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:03:28', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a3fb2712-055b-4f5c-b822-8a681d58fbc1' User entered '98.2'	System	17 Sep 2020 15:03:50
	System	17 Sep 2020 15:03:50



US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:03:35', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a3fb2712-055b-4f5c-b822-8a681d58fbc1' User entered 'No (N)'	System	17 Sep 2020 15:03:50
	System	17 Sep 2020 15:03:50

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:03:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a3fb2712-055b-4f5c-b822-8a681d58fbc1' User entered '17 Sep 2020 11:03'	System	17 Sep 2020 15:03:50
	System	17 Sep 2020 15:03:50

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 10:51'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 13:21'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:22:19', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0e32faed-9d0f-45a8-8515-cff37c970999'	System	18 Sep 2020 01:23:03
User entered 'Yes (Y)'	System	18 Sep 2020 01:23:03

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:22:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0e32faed-9d0f-45a8-8515-cff37c970999' User entered '98.5'	System	18 Sep 2020 01:23:03
	System	18 Sep 2020 01:23:03

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:22:53', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0e32faed-9d0f-45a8-8515-cff37c970999'	System	18 Sep 2020 01:23:03
User entered 'No (N)'	System	18 Sep 2020 01:23:03



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:23:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0e32faed-9d0f-45a8-8515-cff37c970999'	System	18 Sep 2020 01:23:03
User entered '17 Sep 2020 21:23'	System	18 Sep 2020 01:23:03

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 14:16'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 2'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:04:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd90161cc-fd20-4c5d-b9fe-a0f2b6332bbc' User entered 'Yes (Y)'	System	18 Sep 2020 19:05:12
	System	18 Sep 2020 19:05:12

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:04:56', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd90161cc-fd20-4c5d-b9fe-a0f2b6332bbc' User entered '98.0'	System	18 Sep 2020 19:05:12
	System	18 Sep 2020 19:05:12

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:05:02', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd90161cc-fd20-4c5d-b9fe-a0f2b6332bbc'	System	18 Sep 2020 19:05:12
User entered 'No (N)'	System	18 Sep 2020 19:05:12

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:05:07', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd90161cc-fd20-4c5d-b9fe-a0f2b6332bbc'	System	18 Sep 2020 19:05:12
User entered '18 Sep 2020 15:05'	System	18 Sep 2020 19:05:12



US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 3'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:04:16', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c701065c-360f-47e6-99e7-a0ddd5888947' User entered 'Yes (Y)'	System	19 Sep 2020 16:04:38
	System	19 Sep 2020 16:04:38

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:04:24', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c701065c-360f-47e6-99e7-a0ddd5888947' User entered '98.7'	System	19 Sep 2020 16:04:38
	System	19 Sep 2020 16:04:38

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:04:29', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c701065c-360f-47e6-99e7-a0ddd5888947'	System	19 Sep 2020 16:04:38
User entered 'No (N)'	System	19 Sep 2020 16:04:38

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:04:35', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c701065c-360f-47e6-99e7-a0ddd5888947' User entered '19 Sep 2020 12:04'	System	19 Sep 2020 16:04:38
	System	19 Sep 2020 16:04:38

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:41:52



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 4'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:23:27', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2a098c97-cccd-458e-aba8-b77a643a4f4e' User entered 'Yes (Y)'	System	20 Sep 2020 16:23:50
	System	20 Sep 2020 16:23:50

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:23:33', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2a098c97-cccd-458e-aba8-b77a643a4f4e' User entered '97.4'	System	20 Sep 2020 16:23:50
	System	20 Sep 2020 16:23:50

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:23:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2a098c97-cccd-458e-aba8-b77a643a4f4e'	System	20 Sep 2020 16:23:50
User entered 'No (N)'	System	20 Sep 2020 16:23:50

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:23:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2a098c97-cccd-458e-aba8-b77a643a4f4e' User entered '20 Sep 2020 12:23'	System	20 Sep 2020 16:23:50
	System	20 Sep 2020 16:23:50

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:41:52



US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 5'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:07', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2ad0b0ee-d4e9-4fef-a05b-8cf6d81d105b' User entered 'Yes (Y)'	System	21 Sep 2020 20:48:33
	System	21 Sep 2020 20:48:33

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:16', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2ad0b0ee-d4e9-4fef-a05b-8cf6d81d105b' User entered '98.0'	System	21 Sep 2020 20:48:33
	System	21 Sep 2020 20:48:33

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:21', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2ad0b0ee-d4e9-4fef-a05b-8cf6d81d105b'	System	21 Sep 2020 20:48:33
User entered 'No (N)'	System	21 Sep 2020 20:48:33

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:27', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '2ad0b0ee-d4e9-4fef-a05b-8cf6d81d105b' User entered '21 Sep 2020 16:48'	System	21 Sep 2020 20:48:33
	System	21 Sep 2020 20:48:33

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 6'	System	17 Sep 2020 14:41:52



US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:00:41', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f5cb46e0-0928-487e-b028-a7b21cb53ca5' User entered 'Yes (Y)'	System	22 Sep 2020 16:01:52
	System	22 Sep 2020 16:01:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:00:49', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f5cb46e0-0928-487e-b028-a7b21cb53ca5' User entered '97.8'	System	22 Sep 2020 16:01:52
	System	22 Sep 2020 16:01:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:00:54', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f5cb46e0-0928-487e-b028-a7b21cb53ca5'	System	22 Sep 2020 16:01:52
User entered 'No (N)'	System	22 Sep 2020 16:01:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:00:59', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f5cb46e0-0928-487e-b028-a7b21cb53ca5' User entered '22 Sep 2020 12:00'	System	22 Sep 2020 16:01:52
	System	22 Sep 2020 16:01:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 7'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:13', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '6d1276bc-3779-467e-acb9-260990b036ef' User entered 'Yes (Y)'	System	23 Sep 2020 17:06:24
	System	23 Sep 2020 17:06:24



US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:20', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '6d1276bc-3779-467e-acb9-260990b036ef' User entered '97.4'	System	23 Sep 2020 17:06:24
	System	23 Sep 2020 17:06:24

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:25', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '6d1276bc-3779-467e-acb9-260990b036ef' User entered 'No (N)'	System	23 Sep 2020 17:06:24
	System	23 Sep 2020 17:06:24

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:29', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '6d1276bc-3779-467e-acb9-260990b036ef' User entered '23 Sep 2020 13:02'	System	23 Sep 2020 17:06:24
	System	23 Sep 2020 17:06:24

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:04:55', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7cfff225-1021-4374-bc96-019b7cb83f9a'	System	17 Sep 2020 15:05:45
User entered 'None (1)'	System	17 Sep 2020 15:05:45

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:01', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7cfff225-1021-4374-bc96-019b7cb83f9a'	System	17 Sep 2020 15:05:45
User entered 'No (N)'	System	17 Sep 2020 15:05:45



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7cfff225-1021-4374-bc96-019b7cb83f9a'	System	17 Sep 2020 15:05:45
User entered 'No (N)'	System	17 Sep 2020 15:05:45

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:12', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7cfff225-1021-4374-bc96-019b7cb83f9a'	System	17 Sep 2020 15:05:45
User entered 'None (1)'	System	17 Sep 2020 15:05:45

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:19', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '7cfff225-1021-4374-bc96-019b7cb83f9a'	System	17 Sep 2020 15:05:45
User entered '17 Sep 2020 11:05'	System	17 Sep 2020 15:05:45

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 10:51'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 13:21'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:23:18', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ca55debb-f8f6-4501-9acd-3c24be3fe8cf' User entered 'None (1)'	System	18 Sep 2020 01:23:52
	System	18 Sep 2020 01:23:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:23:23', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ca55debb-f8f6-4501-9acd-3c24be3fe8cf' User entered 'No (N)'	System	18 Sep 2020 01:23:52
	System	18 Sep 2020 01:23:52



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:23:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ca55debb-f8f6-4501-9acd-3c24be3fe8cf' User entered 'No (N)'	System	18 Sep 2020 01:23:52
	System	18 Sep 2020 01:23:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:23:39', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ca55debb-f8f6-4501-9acd-3c24be3fe8cf' User entered 'None (1)'	System	18 Sep 2020 01:23:52
	System	18 Sep 2020 01:23:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:23:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'ca55debb-f8f6-4501-9acd-3c24be3fe8cf' User entered '17 Sep 2020 21:23'	System	18 Sep 2020 01:23:52
	System	18 Sep 2020 01:23:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 14:16'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 2'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:05:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'da78546c-9f52-41d1-855a-cce836973921'	System	18 Sep 2020 19:06:06
User entered 'None (1)'	System	18 Sep 2020 19:06:06

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:05:26', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'da78546c-9f52-41d1-855a-cce836973921' User entered 'No (N)'	System	18 Sep 2020 19:06:06
	System	18 Sep 2020 19:06:06



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:05:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'da78546c-9f52-41d1-855a-cce836973921' User entered 'No (N)'	System	18 Sep 2020 19:06:06
	System	18 Sep 2020 19:06:06

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:05:52', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'da78546c-9f52-41d1-855a-cce836973921' User entered 'None (1)'	System	18 Sep 2020 19:06:06
	System	18 Sep 2020 19:06:06

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:02', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'da78546c-9f52-41d1-855a-cce836973921' User entered '18 Sep 2020 15:06'	System	18 Sep 2020 19:06:06
	System	18 Sep 2020 19:06:06

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 3'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:04:44', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9cf48ce-d78c-4230-879d-bc7b16d38e75'	System	19 Sep 2020 16:05:16
User entered 'None (1)'	System	19 Sep 2020 16:05:16

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:04:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9cf48ce-d78c-4230-879d-bc7b16d38e75'	System	19 Sep 2020 16:05:16
User entered 'No (N)'	System	19 Sep 2020 16:05:16



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:04:52', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9cf48ce-d78c-4230-879d-bc7b16d38e75'	System	19 Sep 2020 16:05:16
User entered 'No (N)'	System	19 Sep 2020 16:05:16

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9cf48ce-d78c-4230-879d-bc7b16d38e75'	System	19 Sep 2020 16:05:16
User entered 'None (1)'	System	19 Sep 2020 16:05:16

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:12', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9cf48ce-d78c-4230-879d-bc7b16d38e75'	System	19 Sep 2020 16:05:16
User entered '19 Sep 2020 12:05'	System	19 Sep 2020 16:05:16

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 4'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:23:52', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b9c42e21-1a15-4f29-95e6-6e1a27d6170e' User entered 'None (1)'	System	20 Sep 2020 16:24:18
	System	20 Sep 2020 16:24:18

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:23:55', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b9c42e21-1a15-4f29-95e6-6e1a27d6170e' User entered 'No (N)'	System	20 Sep 2020 16:24:18
	System	20 Sep 2020 16:24:18



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:03', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b9c42e21-1a15-4f29-95e6-6e1a27d6170e' User entered 'No (N)'	System	20 Sep 2020 16:24:18
	System	20 Sep 2020 16:24:18

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b9c42e21-1a15-4f29-95e6-6e1a27d6170e' User entered 'None (1)'	System	20 Sep 2020 16:24:18
	System	20 Sep 2020 16:24:18

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:15', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b9c42e21-1a15-4f29-95e6-6e1a27d6170e' User entered '20 Sep 2020 12:24'	System	20 Sep 2020 16:24:18
	System	20 Sep 2020 16:24:18

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 5'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c7b10ba5-1c29-4c2b-82e8-a376146a6235' User entered 'None (1)'	System	21 Sep 2020 20:49:10
	System	21 Sep 2020 20:49:10

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:41', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c7b10ba5-1c29-4c2b-82e8-a376146a6235'	System	21 Sep 2020 20:49:10
User entered 'No (N)'	System	21 Sep 2020 20:49:10



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:50', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c7b10ba5-1c29-4c2b-82e8-a376146a6235'	System	21 Sep 2020 20:49:10
User entered 'No (N)'	System	21 Sep 2020 20:49:10

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:48:57', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c7b10ba5-1c29-4c2b-82e8-a376146a6235' User entered 'None (1)'	System	21 Sep 2020 20:49:10
	System	21 Sep 2020 20:49:10

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:04', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c7b10ba5-1c29-4c2b-82e8-a376146a6235' User entered '21 Sep 2020 16:49'	System	21 Sep 2020 20:49:10
	System	21 Sep 2020 20:49:10

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 6'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:05', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9a65292-0308-472b-9837-5ecbe3117642'	System	22 Sep 2020 16:02:22
User entered 'None (1)'	System	22 Sep 2020 16:02:22

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:09', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9a65292-0308-472b-9837-5ecbe3117642'	System	22 Sep 2020 16:02:22
User entered 'No (N)'	System	22 Sep 2020 16:02:22



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:12', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9a65292-0308-472b-9837-5ecbe3117642'	System	22 Sep 2020 16:02:22
User entered 'No (N)'	System	22 Sep 2020 16:02:22

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:18', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9a65292-0308-472b-9837-5ecbe3117642'	System	22 Sep 2020 16:02:22
User entered 'None (1)'	System	22 Sep 2020 16:02:22

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c9a65292-0308-472b-9837-5ecbe3117642' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 16:02:22
	System	22 Sep 2020 16:02:22

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 7'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '680973cd-2f54-4b18-851c-cadf46679563'	System	23 Sep 2020 17:06:44
User entered 'None (1)'	System	23 Sep 2020 17:06:44

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:38', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '680973cd-2f54-4b18-851c-cadf46679563'	System	23 Sep 2020 17:06:44
User entered 'No (N)'	System	23 Sep 2020 17:06:44



US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:41', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '680973cd-2f54-4b18-851c-cadf46679563'	System	23 Sep 2020 17:06:44
User entered 'No (N)'	System	23 Sep 2020 17:06:44

US3822119

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:40

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 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '680973cd-2f54-4b18-851c-cadf46679563'	System	23 Sep 2020 17:06:44
User entered 'None (1)'	System	23 Sep 2020 17:06:44

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '680973cd-2f54-4b18-851c-cadf46679563' User entered '23 Sep 2020 13:02'	System	23 Sep 2020 17:06:44
	System	23 Sep 2020 17:06:44

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered 'None (0)'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:35', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered 'None (0)'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:39', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered 'None (0)'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered 'None (0)'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered 'None (0)'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered 'None (0)'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:54', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered 'No (N)'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T11:05:59', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a54180a-6150-45b4-865d-f6c5e73750ce' User entered '17 Sep 2020 11:05'	System	17 Sep 2020 15:06:09
	System	17 Sep 2020 15:06:09

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 10:51'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 13:21'	System	17 Sep 2020 14:41:52



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:23:58', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5' User entered 'None (0)'	System	18 Sep 2020 01:25:34
	System	18 Sep 2020 01:25:34

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:24:19', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5'	System	18 Sep 2020 01:25:34
User entered 'Some interference with activity (2)'	System	18 Sep 2020 01:25:34

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:24:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5'	System	18 Sep 2020 01:25:34
User entered 'No interference with activity (1)'	System	18 Sep 2020 01:25:34

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:24:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5'	System	18 Sep 2020 01:25:34
User entered 'No interference with activity (1)'	System	18 Sep 2020 01:25:34

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:24:56', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5' User entered 'None (0)'	System	18 Sep 2020 01:25:34
	System	18 Sep 2020 01:25:34

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:25:02', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5' User entered 'None (0)'	System	18 Sep 2020 01:25:34
	System	18 Sep 2020 01:25:34

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:25:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5' User entered 'No (N)'	System	18 Sep 2020 01:25:34
	System	18 Sep 2020 01:25:34



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-17T21:25:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '523411f5-35ca-4f94-8d6c-b7c382ee6aa5'	System	18 Sep 2020 01:25:34
User entered '17 Sep 2020 21:25'	System	18 Sep 2020 01:25:34

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '17 Sep 2020 14:16'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 2'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eae4-56c7-44b6-8247-a84d6e3bb7c9' User entered 'None (0)'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:12', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eaed4-56c7-44b6-8247-a84d6e3bb7c9' User entered 'None (0)'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:17', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eae4-56c7-44b6-8247-a84d6e3bb7c9' User entered 'None (0)'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eae4-56c7-44b6-8247-a84d6e3bb7c9' User entered 'None (0)'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:32', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eaed4-56c7-44b6-8247-a84d6e3bb7c9' User entered 'None (0)'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:36', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eae4-56c7-44b6-8247-a84d6e3bb7c9' User entered 'None (0)'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eae4-56c7-44b6-8247-a84d6e3bb7c9' User entered 'No (N)'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-18T15:06:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0d8eae4-56c7-44b6-8247-a84d6e3bb7c9' User entered '18 Sep 2020 15:06'	System	18 Sep 2020 19:06:50
	System	18 Sep 2020 19:06:50

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 3'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:20', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e' User entered 'None (0)'	System	19 Sep 2020 16:06:11
	System	19 Sep 2020 16:06:11



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e'	System	19 Sep 2020 16:06:11
User entered 'No interference with activity (1)'	System	19 Sep 2020 16:06:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e' User entered 'No interference with activity (1)'	System	19 Sep 2020 16:06:11
	System	19 Sep 2020 16:06:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:43', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e'	System	19 Sep 2020 16:06:11
User entered 'No interference with activity (1)'	System	19 Sep 2020 16:06:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:49', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e' User entered 'None (0)'	System	19 Sep 2020 16:06:11
	System	19 Sep 2020 16:06:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:05:53', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e' User entered 'None (0)'	System	19 Sep 2020 16:06:11
	System	19 Sep 2020 16:06:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:06:03', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e' User entered 'No (N)'	System	19 Sep 2020 16:06:11
	System	19 Sep 2020 16:06:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-19T12:06:09', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '477432ac-3ff2-4fe4-93f8-005ba22c5e1e' User entered '19 Sep 2020 12:06'	System	19 Sep 2020 16:06:11
	System	19 Sep 2020 16:06:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:41:52



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 4'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:26', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c' User entered 'None (0)'	System	20 Sep 2020 16:25:00
	System	20 Sep 2020 16:25:00

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c'	System	20 Sep 2020 16:25:00
User entered 'No interference with activity (1)'	System	20 Sep 2020 16:25:00

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c'	System	20 Sep 2020 16:25:00
User entered 'No interference with activity (1)'	System	20 Sep 2020 16:25:00

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:41', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c'	System	20 Sep 2020 16:25:00
User entered 'No interference with activity (1)'	System	20 Sep 2020 16:25:00

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:44', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c' User entered 'None (0)'	System	20 Sep 2020 16:25:00
	System	20 Sep 2020 16:25:00

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:47', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c' User entered 'None (0)'	System	20 Sep 2020 16:25:00
	System	20 Sep 2020 16:25:00



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:52', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c' User entered 'No (N)'	System	20 Sep 2020 16:25:00
	System	20 Sep 2020 16:25:00

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-20T12:24:57', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '363da24c-1768-499e-b2e8-d4038165752c' User entered '20 Sep 2020 12:24'	System	20 Sep 2020 16:25:00
	System	20 Sep 2020 16:25:00

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 5'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered 'None (0)'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:14', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered 'None (0)'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:19', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered 'None (0)'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:23', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered 'None (0)'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:26', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered 'None (0)'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:30', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered 'None (0)'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:35', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered 'No (N)'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-21T16:49:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e18da149-e05e-4918-8278-8eed866c35a1' User entered '21 Sep 2020 16:49'	System	21 Sep 2020 20:49:45
	System	21 Sep 2020 20:49:45

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 6'	System	17 Sep 2020 14:41:52



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:28', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43' User entered 'None (0)'	System	22 Sep 2020 16:03:11
	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:32', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43'	System	22 Sep 2020 16:03:11
User entered 'No interference with activity (1)'	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:36', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43' User entered 'None (0)'	System	22 Sep 2020 16:03:11
	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:40', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43'	System	22 Sep 2020 16:03:11
User entered 'No interference with activity (1)'	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:43', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43' User entered 'None (0)'	System	22 Sep 2020 16:03:11
	System	22 Sep 2020 16:03:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:47', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43' User entered 'None (0)'	System	22 Sep 2020 16:03:11
	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43' User entered 'No (N)'	System	22 Sep 2020 16:03:11
	System	22 Sep 2020 16:03:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-22T12:01:58', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '0b30059a-615a-4173-b9ad-30c99d7fda43' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 16:03:11
	System	22 Sep 2020 16:03:11



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	17 Sep 2020 14:41:52
User entered 'Day 7'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:02:57', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f' User entered 'None (0)'	System	23 Sep 2020 17:07:37
	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:03:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f'	System	23 Sep 2020 17:07:37
User entered 'No interference with activity (1)'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:03:36', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f'	System	23 Sep 2020 17:07:37
User entered 'No interference with activity (1)'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:03:14', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f' User entered 'No interference with activity (1)'	System	23 Sep 2020 17:07:37
	System	23 Sep 2020 17:07:37

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:03:18', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f' User entered 'None (0)'	System	23 Sep 2020 17:07:37
	System	23 Sep 2020 17:07:37



US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:03:21', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f' User entered 'None (0)'	System	23 Sep 2020 17:07:37
	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:03:25', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f' User entered 'No (N)'	System	23 Sep 2020 17:07:37
	System	23 Sep 2020 17:07:37

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-23T13:03:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b98aa262-8ee5-44bc-a882-a949c1bfa06f' User entered '23 Sep 2020 13:03'	System	23 Sep 2020 17:07:37
	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:41:52

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:41:52

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	22 Sep 2020 16:03:11
User entered 'Day 8'	System	22 Sep 2020 16:03:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:38:23', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c6f28ad5-7d60-43ff-a9d0-1be4ecff87fd' User entered 'No interference with activity (1)'	System	24 Sep 2020 16:38:38
	System	24 Sep 2020 16:38:38

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:38:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c6f28ad5-7d60-43ff-a9d0-1be4ecff87fd'	System	24 Sep 2020 16:38:38
User entered '24 Sep 2020 12:38'	System	24 Sep 2020 16:38:38



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:03:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	23 Sep 2020 17:07:37
User entered 'Day 9'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:23:12', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b5059d5c-dbf1-40f8-b4ce-fb17784e1760'	System	25 Sep 2020 19:23:28
User entered 'No interference with activity (1)'	System	25 Sep 2020 19:23:28

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:23:23', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b5059d5c-dbf1-40f8-b4ce-fb17784e1760' User entered '25 Sep 2020 15:23'	System	25 Sep 2020 19:23:28
	System	25 Sep 2020 19:23:28

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 17:07:37

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	24 Sep 2020 16:38:38
User entered 'Day 10'	System	24 Sep 2020 16:38:38



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-26T13:33:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'fe604236-4b47-4619-8bee-a6c9bc270b33'	System	26 Sep 2020 17:33:08
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:33:08

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-26T13:33:03', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'fe604236-4b47-4619-8bee-a6c9bc270b33' User entered '26 Sep 2020 13:33'	System	26 Sep 2020 17:33:08
	System	26 Sep 2020 17:33:08

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:38:38

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:38:38

US3822119

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	25 Sep 2020 19:23:28
User entered 'Day 11'	System	25 Sep 2020 19:23:28

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-27T18:55:36', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b47fcdf2-2f8b-4741-8f4c-9c32eac7384f' User entered 'None (0)'	System	27 Sep 2020 22:55:44
	System	27 Sep 2020 22:55:44

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-27T18:55:40', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b47fcaf2-2f8b-4741-8f4c-9c32eac7384f' User entered '27 Sep 2020 18:55'	System	27 Sep 2020 22:55:44
	System	27 Sep 2020 22:55:44

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 19:23:28



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 19:23:28

US3822119

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	23 Sep 2020 17:07:37
User entered 'Day 8'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:53:40

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:39:19', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3672d270-f28e-48b0-84af-b2ee22175613'	System	24 Sep 2020 16:39:27
User entered 'No interference with activity (1)'	System	24 Sep 2020 16:39:27

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:39:25', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3672d270-f28e-48b0-84af-b2ee22175613' User entered '24 Sep 2020 12:39'	System	24 Sep 2020 16:39:27
	System	24 Sep 2020 16:39:27

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 17:07:37

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	23 Sep 2020 17:07:37
User entered 'Day 9'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:23:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '45c0bc43-d354-4d6e-a0f5-28112fab088e' User entered 'None (0)'	System	25 Sep 2020 19:23:38
	System	25 Sep 2020 19:23:38



US3822119

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:23:35', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '45c0bc43-d354-4d6e-a0f5-28112fab088e' User entered '25 Sep 2020 15:23'	System	25 Sep 2020 19:23:38
	System	25 Sep 2020 19:23:38

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 17:07:37

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	22 Sep 2020 16:03:11
User entered 'Day 8'	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:53:40

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:38:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'fb7bbd34-d0ed-44c9-b997-d38836af0e92'	System	24 Sep 2020 16:39:12
User entered 'No interference with activity (1)'	System	24 Sep 2020 16:39:12

US3822119

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:39:09', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'fb7bbd34-d0ed-44c9-b997-d38836af0e92'	System	24 Sep 2020 16:39:12
User entered '24 Sep 2020 12:39'	System	24 Sep 2020 16:39:12

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:03:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:03:11



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	23 Sep 2020 17:07:37
User entered 'Day 9'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:23:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '30117833-8148-4bcf-bb54-04b88dd7d7e6' User entered 'None (0)'	System	25 Sep 2020 19:23:55
	System	25 Sep 2020 19:23:55

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:23:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '30117833-8148-4bcf-bb54-04b88dd7d7e6'	System	25 Sep 2020 19:23:55
User entered '25 Sep 2020 15:23'	System	25 Sep 2020 19:23:55

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 17:07:37

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	22 Sep 2020 16:03:11
User entered 'Day 8'	System	22 Sep 2020 16:03:11

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:39:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9341735c-19f4-495c-85dc-0a5e9353f647'	System	24 Sep 2020 16:39:40
User entered 'No (N)'	System	24 Sep 2020 16:39:40

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:53:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-24T12:39:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9341735c-19f4-495c-85dc-0a5e9353f647'	System	24 Sep 2020 16:39:40
User entered '24 Sep 2020 12:39'	System	24 Sep 2020 16:39:40



**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:03:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:03:11

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	23 Sep 2020 17:07:37
User entered 'Day 9'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:23:58', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd928f4b9-605e-4bec-a281-5e2038aca564' User entered 'No (N)'	System	25 Sep 2020 19:24:07
	System	25 Sep 2020 19:24:07

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-25T15:24:01', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'd928f4b9-605e-4bec-a281-5e2038aca564' User entered '25 Sep 2020 15:24'	System	25 Sep 2020 19:24:07
	System	25 Sep 2020 19:24:07

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 17:07:37

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 17:07:37

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	25 Sep 2020 19:23:28
User entered 'Day 11'	System	25 Sep 2020 19:23:28



US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:53:40

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-27T18:55:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'aac540d-f94b-4ec9-b810-4db775842e59'	System	27 Sep 2020 22:55:51
User entered 'No (N)'	System	27 Sep 2020 22:55:51

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-09-27T18:55:49', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'aac540d-f94b-4ec9-b810-4db775842e59'	System	27 Sep 2020 22:55:51
User entered '27 Sep 2020 18:55'	System	27 Sep 2020 22:55:51

**US3822119**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 10 Jun 2021 09:53:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 19:23:28

US3822119

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 09:53:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 19:23:28

**US3822119**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:52:16

US3822119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 07:09:43
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Due to scheudling error pt was called out of window' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 11:52:43
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Oct 2020 11:52:16
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 11:52:16

**US3822119**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:52:16

US3822119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:52:16



US3822119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:52:48

**US3822119**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User entered 'I'	System	13 Oct 2020 11:52:48

**US3822119**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:52:59

US3822119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 07:10:31
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Due to scheudling error pt was called out of window' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 11:53:03
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Oct 2020 11:52:59
User entered '5 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 11:52:59

US3822119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:52:59

**US3822119**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:52:59

**US3822119**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:53:08

**US3822119**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User entered 'I'	System	13 Oct 2020 11:53:08



US3822119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Per GCL Lab Reconciliation: Immunogenicity form is blank, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 21OCT2020, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 11:04:04
Query 'Per GCL Lab Reconciliation: Immunogenicity form is blank, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 21OCT2020, per GCL. Please clarify and update as appropriate.' answered with 'added' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:29:13
User opened query 'Per GCL Lab Reconciliation: Immunogenicity form is blank, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 21OCT2020, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:03:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:53:17

US3822119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 07:10:12
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Due to scheudling error pt was called out of window' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 11:53:20
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Oct 2020 11:53:17
User entered '12 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 11:53:17

**US3822119**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:53:17

**US3822119**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:53:17

US3822119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:48:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 11:53:25

**US3822119**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 21:44:07
User entered 'I'	System	13 Oct 2020 11:53:25

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:04

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '21 Oct 2020'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:04



US3822119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[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 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:04

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'VISIT3'	System	10 Nov 2020 20:11:04

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '21 Oct 2020'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '11:25'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '21 Oct 2020 11:25'	System	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '97.0' F	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36



**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '65'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'bpm'	System	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '14'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'breaths/min'	System	10 Nov 2020 20:11:36

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '127'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '75'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:36



US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'mmHg'	System	10 Nov 2020 20:11:36

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04

US3822119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04

US3822119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Nov 2020 20:11:49

US3822119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:11:49

US3822119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Nov 2020 20:12:00

US3822119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '21 Oct 2020'	Kelly Woodell (b) (4)	10 Nov 2020 20:12:00

US3822119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered '11:36'	Kelly Woodell (b) (4)	10 Nov 2020 20:12:00



**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered '21 Oct 2020 11:36'	System	10 Nov 2020 20:12:00

**US3822119**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 22:50:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Nov 2020 20:12:05

US3822119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'I'	System	10 Nov 2020 20:12:05

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 64'	System	13 Aug 2020 16:45:02

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-14T09:20:38', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9f94709e-61b4-4579-8130-c895a8682f34'	System	14 Oct 2020 13:20:53
User entered 'No (N)'	System	14 Oct 2020 13:20:53

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-14T09:20:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9f94709e-61b4-4579-8130-c895a8682f34'	System	14 Oct 2020 13:20:53
User entered 'No (N)'	System	14 Oct 2020 13:20:53

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-14T09:20:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '9f94709e-61b4-4579-8130-c895a8682f34' User entered '14 Oct 2020 09:20:48'	System	14 Oct 2020 13:20:53
	System	14 Oct 2020 13:20:53

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 16:45:02



**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 71'	System	13 Aug 2020 16:45:02

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-20T12:38:50', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '4cbd4b9c-0e9a-4920-bf13-99cb30a87c74'	System	20 Oct 2020 16:39:12
User entered 'No (N)'	System	20 Oct 2020 16:39:12

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-20T12:38:56', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '4cbd4b9c-0e9a-4920-bf13-99cb30a87c74'	System	20 Oct 2020 16:39:12
User entered 'No (N)'	System	20 Oct 2020 16:39:12

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-20T12:39:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '4cbd4b9c-0e9a-4920-bf13-99cb30a87c74' User entered '20 Oct 2020 12:39:08'	System	20 Oct 2020 16:39:12
	System	20 Oct 2020 16:39:12

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 78'	System	13 Aug 2020 16:45:02



US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-29T11:03:04', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5d300f3a-a3d8-44e1-a5e1-f2c9c8f19658'	System	29 Oct 2020 15:03:26
User entered 'No (N)'	System	29 Oct 2020 15:03:26

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-29T11:03:11', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5d300f3a-a3d8-44e1-a5e1-f2c9c8f19658'	System	29 Oct 2020 15:03:26
User entered 'No (N)'	System	29 Oct 2020 15:03:26

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-10-29T11:03:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5d300f3a-a3d8-44e1-a5e1-f2c9c8f19658' User entered '29 Oct 2020 11:03:22'	System	29 Oct 2020 15:03:26
	System	29 Oct 2020 15:03:26

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 92'	System	13 Aug 2020 16:45:02

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-10T09:12:38', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '1c6fb3c8-749f-47d4-a557-50bf6228ca5c'	System	10 Nov 2020 14:12:53
User entered 'No (N)'	System	10 Nov 2020 14:12:53

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-10T09:12:43', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '1c6fb3c8-749f-47d4-a557-50bf6228ca5c'	System	10 Nov 2020 14:12:53
User entered 'No (N)'	System	10 Nov 2020 14:12:53



**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-10T09:12:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '1c6fb3c8-749f-47d4-a557-50bf6228ca5c' User entered '10 Nov 2020 09:12:48'	System	10 Nov 2020 14:12:53
	System	10 Nov 2020 14:12:53

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered 'Day 99'	System	13 Aug 2020 16:45:02

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-17T22:40:33', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c8fdaade-8dd5-4950-b334-9799f317ea06'	System	18 Nov 2020 03:40:53
User entered 'No (N)'	System	18 Nov 2020 03:40:53

US3822119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-17T22:40:43', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c8fdaade-8dd5-4950-b334-9799f317ea06'	System	18 Nov 2020 03:40:53
User entered 'No (N)'	System	18 Nov 2020 03:40:53

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-17T22:40:49', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'c8fdaade-8dd5-4950-b334-9799f317ea06' User entered '17 Nov 2020 22:40:49'	System	18 Nov 2020 03:40:53
	System	18 Nov 2020 03:40:53

**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 16:45:02



**US3822119**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:07:18
Data entry locked.	System	13 Aug 2020 16:45:02
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 16:45:02

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-24T19:10:24', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3cfbfa13-5eea-468f-a817-767b67ed7bb6'	System	25 Nov 2020 00:10:43
User entered 'No (N)'	System	25 Nov 2020 00:10:43

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-24T19:10:30', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3cfbfa13-5eea-468f-a817-767b67ed7bb6'	System	25 Nov 2020 00:10:43
User entered 'No (N)'	System	25 Nov 2020 00:10:43

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-11-24T19:10:39', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3cfbfa13-5eea-468f-a817-767b67ed7bb6' User entered '24 Nov 2020 19:10:39'	System	25 Nov 2020 00:10:43

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-01T18:42:51', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '237f8d4c-a8f0-42a2-a518-62ab75fe619e' User entered 'No (N)'	System	01 Dec 2020 23:43:08

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-01T18:42:59', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '237f8d4c-a8f0-42a2-a518-62ab75fe619e' User entered 'No (N)'	System	01 Dec 2020 23:43:08

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-01T18:43:05', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '237f8d4c-a8f0-42a2-a518-62ab75fe619e' User entered '01 Dec 2020 18:43:05'	System	01 Dec 2020 23:43:08
	System	01 Dec 2020 23:43:08

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-07T09:56:37', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f5e39f7f-1242-4aa3-b262-228fb96321cb' User entered 'No (N)'	System	07 Dec 2020 14:57:01
	System	07 Dec 2020 14:57:01

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-07T09:56:55', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f5e39f7f-1242-4aa3-b262-228fb96321cb' User entered 'No (N)'	System	07 Dec 2020 14:57:01
	System	07 Dec 2020 14:57:01



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-07T09:57:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f5e39f7f-1242-4aa3-b262-228fb96321cb' User entered '07 Dec 2020 09:57:00'	System	07 Dec 2020 14:57:01
	System	07 Dec 2020 14:57:01

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-14T12:00:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '4b7583a6-eed9-4a0c-97f0-e948e94c5066'	System	14 Dec 2020 17:01:00
User entered 'No (N)'	System	14 Dec 2020 17:01:00

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-14T12:00:48', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '4b7583a6-eed9-4a0c-97f0-e948e94c5066'	System	14 Dec 2020 17:01:00
User entered 'No (N)'	System	14 Dec 2020 17:01:00

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-14T12:00:53', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '4b7583a6-eed9-4a0c-97f0-e948e94c5066'	System	14 Dec 2020 17:01:00
User entered '14 Dec 2020 12:00:53'	System	14 Dec 2020 17:01:00

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-19T11:20:32', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '93361df7-8c5d-4306-852f-05506349b805' User entered 'No (N)'	System	19 Dec 2020 16:20:43
	System	19 Dec 2020 16:20:43

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-19T11:20:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '93361df7-8c5d-4306-852f-05506349b805'	System	19 Dec 2020 16:20:43
User entered 'No (N)'	System	19 Dec 2020 16:20:43

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-19T11:20:39', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '93361df7-8c5d-4306-852f-05506349b805' User entered '19 Dec 2020 11:20:39'	System	19 Dec 2020 16:20:43
	System	19 Dec 2020 16:20:43

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-27T11:25:42', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'dc38c7ba-f8cc-4f27-8681-4c054b4853f0' User entered 'No (N)'	System	27 Dec 2020 16:26:02
	System	27 Dec 2020 16:26:02

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-27T11:25:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'dc38c7ba-f8cc-4f27-8681-4c054b4853f0' User entered 'No (N)'	System	27 Dec 2020 16:26:02
	System	27 Dec 2020 16:26:02

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2020-12-27T11:25:58', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'dc38c7ba-f8cc-4f27-8681-4c054b4853f0' User entered '27 Dec 2020 11:25:58'	System	27 Dec 2020 16:26:02
	System	27 Dec 2020 16:26:02

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-04T13:42:56', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '42a668df-c115-4c74-8e7b-d0c8bec6afe2' User entered 'No (N)'	System	04 Jan 2021 18:43:10

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-04T13:43:03', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '42a668df-c115-4c74-8e7b-d0c8bec6afe2'	System	04 Jan 2021 18:43:10
User entered 'No (N)'	System	04 Jan 2021 18:43:10



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-04T13:43:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '42a668df-c115-4c74-8e7b-d0c8bec6afe2' User entered '04 Jan 2021 13:43:08'	System	04 Jan 2021 18:43:10
	System	04 Jan 2021 18:43:10

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-12T11:50:20', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12d7ab68-8afb-40b8-ab4f-4c231b09e01e' User entered 'No (N)'	System	12 Jan 2021 16:50:28
	System	12 Jan 2021 16:50:28

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-12T11:50:22', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12d7ab68-8afb-40b8-ab4f-4c231b09e01e' User entered 'No (N)'	System	12 Jan 2021 16:50:28
	System	12 Jan 2021 16:50:28

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-12T11:50:26', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '12d7ab68-8afb-40b8-ab4f-4c231b09e01e' User entered '12 Jan 2021 11:50:26'	System	12 Jan 2021 16:50:28
	System	12 Jan 2021 16:50:28

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-17T21:48:03', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f9997fbf-8e40-4087-b326-802b7da99dd9' User entered 'No (N)'	System	18 Jan 2021 02:48:15
	System	18 Jan 2021 02:48:15

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-17T21:48:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f9997fbf-8e40-4087-b326-802b7da99dd9'	System	18 Jan 2021 02:48:15
User entered 'No (N)'	System	18 Jan 2021 02:48:15

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-17T21:48:13', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f9997fbf-8e40-4087-b326-802b7da99dd9' User entered '17 Jan 2021 21:48:13'	System	18 Jan 2021 02:48:15

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:12:58', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered 'Yes (Y)'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:13:08', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered 'No (N)'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:13:31', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered 'Yes (Y)'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '1'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered '1'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '1'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered '1'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '1'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:10', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '0'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:23', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242'	System	25 Jan 2021 03:14:57
User entered 'No (N)'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-01-24T22:14:45', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '5e689cf9-59ce-49fa-a283-0750c7e23242' User entered '24 Jan 2021 22:14:45'	System	25 Jan 2021 03:14:57

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-01T21:14:18', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '020b9e5f-1ee2-420f-be4f-e66c915b4e54'	System	02 Feb 2021 02:16:13
User entered 'No (N)'	System	02 Feb 2021 02:16:13

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-01T21:14:21', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '020b9e5f-1ee2-420f-be4f-e66c915b4e54'	System	02 Feb 2021 02:16:13
User entered 'No (N)'	System	02 Feb 2021 02:16:13

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-01T21:14:30', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '020b9e5f-1ee2-420f-be4f-e66c915b4e54'	System	02 Feb 2021 02:16:13
User entered '01 Feb 2021 21:14:30'	System	02 Feb 2021 02:16:13

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-07T19:18:35', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f7453c14-7523-4563-95f0-fd0642097601' User entered 'No (N)'	System	08 Feb 2021 00:18:49
	System	08 Feb 2021 00:18:49

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-07T19:18:41', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f7453c14-7523-4563-95f0-fd0642097601' User entered 'No (N)'	System	08 Feb 2021 00:18:49
	System	08 Feb 2021 00:18:49

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-07T19:18:46', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'f7453c14-7523-4563-95f0-fd0642097601' User entered '07 Feb 2021 19:18:46'	System	08 Feb 2021 00:18:49

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-15T12:59:20', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b94c991a-bfe9-469d-832f-37df198a26a0'	System	15 Feb 2021 17:59:37
User entered 'No (N)'	System	15 Feb 2021 17:59:37

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-15T12:59:24', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b94c991a-bfe9-469d-832f-37df198a26a0'	System	15 Feb 2021 17:59:37
User entered 'No (N)'	System	15 Feb 2021 17:59:37



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-15T12:59:34', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'b94c991a-bfe9-469d-832f-37df198a26a0' User entered '15 Feb 2021 12:59:34'	System	15 Feb 2021 17:59:37
	System	15 Feb 2021 17:59:37

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-21T21:25:20', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'dd7f7f15-fd45-4fce-a531-9edd5355c8ca' User entered 'No (N)'	System	22 Feb 2021 02:27:35
	System	22 Feb 2021 02:27:35

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-21T21:25:23', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'dd7f7f15-fd45-4fce-a531-9edd5355c8ca' User entered 'No (N)'	System	22 Feb 2021 02:27:35

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-21T21:25:28', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'dd7f7f15-fd45-4fce-a531-9edd5355c8ca' User entered '21 Feb 2021 21:25:28'	System	22 Feb 2021 02:27:35

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-27T22:44:27-05:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'acbb71c7-b4a0-4ac4-bf50-bfcdffaec011' User entered 'No (N)'	System	28 Feb 2021 03:44:48

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-27T22:44:35-05:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'acbb71c7-b4a0-4ac4-bf50-bfcdffaec011' User entered 'No (N)'	System	28 Feb 2021 03:44:48

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-02-27T22:44:42-05:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'acbb71c7-b4a0-4ac4-bf50-bfcdffaec011' User entered '28 Feb 2021 03:44:42'	System	28 Feb 2021 03:44:48

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-06T11:38:14-05:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e0c1b098-028d-40fe-b601-d3ca7e3b02ba' User entered 'No (N)'	System	06 Mar 2021 16:38:31

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-06T11:38:19-05:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e0c1b098-028d-40fe-b601-d3ca7e3b02ba'	System	06 Mar 2021 16:38:31
User entered 'No (N)'	System	06 Mar 2021 16:38:31

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-06T11:38:25-05:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'e0c1b098-028d-40fe-b601-d3ca7e3b02ba' User entered '06 Mar 2021 11:38:25'	System	06 Mar 2021 16:38:31
	System	06 Mar 2021 16:38:31

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-15T10:03:16-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a9750320-4252-4397-b4dd-4c8f800c436c'	System	15 Mar 2021 14:03:36
User entered 'No (N)'	System	15 Mar 2021 14:03:36

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-15T10:03:26-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a9750320-4252-4397-b4dd-4c8f800c436c'	System	15 Mar 2021 14:03:36
User entered 'No (N)'	System	15 Mar 2021 14:03:36



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-15T10:03:31-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a9750320-4252-4397-b4dd-4c8f800c436c' User entered '15 Mar 2021 10:03:31'	System	15 Mar 2021 14:03:36
	System	15 Mar 2021 14:03:36

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-22T15:08:29-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a763f7b-66db-4905-aa95-b6af51bc12a9' User entered 'No (N)'	System	22 Mar 2021 19:08:48
	System	22 Mar 2021 19:08:48

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-22T15:08:32-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a763f7b-66db-4905-aa95-b6af51bc12a9'	System	22 Mar 2021 19:08:48
User entered 'No (N)'	System	22 Mar 2021 19:08:48

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-22T15:08:43-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '3a763f7b-66db-4905-aa95-b6af51bc12a9' User entered '22 Mar 2021 15:08:43'	System	22 Mar 2021 19:08:48
	System	22 Mar 2021 19:08:48

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-27T05:47:30-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'bd796449-4075-41bc-b426-c1854c70babc'	System	27 Mar 2021 09:48:02
User entered 'No (N)'	System	27 Mar 2021 09:48:02

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-27T05:47:44-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'bd796449-4075-41bc-b426-c1854c70babc'	System	27 Mar 2021 09:48:02
User entered 'No (N)'	System	27 Mar 2021 09:48:02

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-03-27T05:47:52-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'bd796449-4075-41bc-b426-c1854c70babc' User entered '27 Mar 2021 05:47:52'	System	27 Mar 2021 09:48:02
	System	27 Mar 2021 09:48:02

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-06T17:59:45-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'affeeb8d-ce9d-407d-ba9f-0a8743d0a237'	System	06 Apr 2021 21:59:58
User entered 'No (N)'	System	06 Apr 2021 21:59:58

US3822119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-06T17:59:48-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'affeeb8d-ce9d-407d-ba9f-0a8743d0a237'	System	06 Apr 2021 21:59:58
User entered 'No (N)'	System	06 Apr 2021 21:59:58

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-06T17:59:53-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'affeeb8d-ce9d-407d-ba9f-0a8743d0a237'	System	06 Apr 2021 21:59:58
User entered '06 Apr 2021 17:59:53'	System	06 Apr 2021 21:59:58

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-12T20:16:11-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'fc2fa05f-9f31-405f-9edb-d4efe809cd10'	System	13 Apr 2021 00:16:27
User entered 'No (N)'	System	13 Apr 2021 00:16:27

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-12T20:16:16-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'fc2fa05f-9f31-405f-9edb-d4efe809cd10'	System	13 Apr 2021 00:16:27
User entered 'No (N)'	System	13 Apr 2021 00:16:27



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-12T20:16:23-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'fc2fa05f-9f31-405f-9edb-d4efe809cd10'	System	13 Apr 2021 00:16:27
User entered '12 Apr 2021 20:16:23'	System	13 Apr 2021 00:16:27

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-18T18:53:22-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '6ce15383-662d-4bd1-9b8c-c85165f9f4ac' User entered 'No (N)'	System	18 Apr 2021 22:53:33

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-18T18:53:25-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '6ce15383-662d-4bd1-9b8c-c85165f9f4ac'	System	18 Apr 2021 22:53:33
User entered 'No (N)'	System	18 Apr 2021 22:53:33

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-04-18T18:53:29-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: '6ce15383-662d-4bd1-9b8c-c85165f9f4ac' User entered '18 Apr 2021 18:53:29'	System	18 Apr 2021 22:53:33
	System	18 Apr 2021 22:53:33

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-05-01T09:27:47-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a77270e4-08c8-4ab4-be30-af34b9e91aab'	System	01 May 2021 13:28:09
User entered 'No (N)'	System	01 May 2021 13:28:09

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-05-01T09:27:51-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a77270e4-08c8-4ab4-be30-af34b9e91aab'	System	01 May 2021 13:28:09
User entered 'No (N)'	System	01 May 2021 13:28:09

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8C2D3CF8-A36B-49CD-AE45-3BCE1B13CF2E)', Time: '2021-05-01T09:28:06-04:00', User OID: 'PatientReportedOutcome (US3822119)', ODM File OID: 'a77270e4-08c8-4ab4-be30-af34b9e91aab'	System	01 May 2021 13:28:09
User entered '01 May 2021 09:28:06'	System	01 May 2021 13:28:09



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:08:19



**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:08:19
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:08:19

**US3822119**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:11:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:05

**US3822119**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:11:03
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:05



**US3822119**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:11:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:05

**US3822119**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:11:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:05

**US3822119**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:11:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:08

**US3822119**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:15:04
User entered 'I'	System	11 Jan 2021 12:54:08

**US3822119**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:19

**US3822119**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:19

**US3822119**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:19

**US3822119**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:19



**US3822119**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:54:21

**US3822119**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered 'I'	System	11 Jan 2021 12:54:21

**US3822119**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 15:22:55

US3822119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Query 'Per CDM: Safety call day 149 "Date of Contact or Contact Attempt" is greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Kindly review and update the data as appropriate, else clarify. Thankyou.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:39:07
User opened query 'Per CDM: Safety call day 149 "Date of Contact or Contact Attempt" is greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Kindly review and update the data as appropriate, else clarify. Thankyou.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:21:13
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 18:07:13
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Date is correct' (Site from System).	Kelly Woodell (b) (4) (b) (4)	27 Jan 2021 15:23:06
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	27 Jan 2021 15:22:55
User entered '11 Jan 2021'	Kelly Woodell (b) (4) (b) (4)	27 Jan 2021 15:22:55

**US3822119**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	27 Jan 2021 15:22:55

**US3822119**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	Kelly Woodell (b) (4)	27 Jan 2021 15:22:55

**US3822119**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 15:23:11

**US3822119**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered 'I'	System	27 Jan 2021 15:23:11



**US3822119**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:58:26

US3822119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 11:09:19
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety call is 4 days out of window, deviation noted. ' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 13:59:17
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Feb 2021 13:58:26
User entered '08 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 13:58:26

**US3822119**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:58:26

**US3822119**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:58:26

**US3822119**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:58:14

**US3822119**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered 'I'	System	09 Feb 2021 13:58:14

US3822119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:39

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:39



US3822119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:39

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered 'VISIT4'	System	19 Mar 2021 17:44:39

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered empty.	System	01 Apr 2021 15:36:22

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22



**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered empty.	System	01 Apr 2021 15:36:22

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered empty.	System	01 Apr 2021 15:36:22

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered empty.	System	01 Apr 2021 15:36:22

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:36:22



**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered empty.	System	01 Apr 2021 15:36:22

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57

US3822119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57

US3822119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:43

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:53:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:43

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:58

US3822119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:58

US3822119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered '10:40'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:44:58



**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered '19 Mar 2021 10:40'	System	19 Mar 2021 17:44:58

US3822119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:45:02

**US3822119**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:57
User entered 'I'	System	19 Mar 2021 17:45:02

US3822119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:01:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:30:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 13:30:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:30:16
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 13:30:11
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 13:30:11

US3822119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 16:07:53
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:01:28
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'visit is in the window, 207 days from visit 2 treatment.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:32:11
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Apr 2021 13:30:11
User entered '05 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 13:30:11

**US3822119**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:01:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:30:11

**US3822119**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:01:28
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:30:11

US3822119

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:01:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:32:15



**US3822119**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 13:32:15

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:08:02

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:08:02

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Jan 2021 20:08:02

**US3822119**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 20:08:02

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:01:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 17:06:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:11

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:08:17



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User closed query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 03:49:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:01:28
	(b) (4)	
Query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:06:55
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 17:06:48
User opened query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:59:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:11

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:36:49
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:31:02
User closed query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:04:33
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Subject was scheduled for the visit prior to being unblinded. The subject was unblinded the evening prior to the their scheduled visit. They were not notified of their randomization assignment until after signing the amendment 6 ICF and requesting to be unblinded.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 18:05:51
Query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' answered with 'updated per IRT' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 18:05:29
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	19 Apr 2021 18:05:07
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 18:05:07
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 18:05:07
User opened query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:09:03
User closed query 'Per CDM : Per IRT : subject was unblinded on 21JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:09:03

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Query 'Per CDM : Per IRT : subject was unblinded on 21JAN2021. Please review and reconcile. ' answered with 'Subject unblinding in IRT done on 21JAN2021 but SUBJECT was actually unblinded in clinic 22JAN2021. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:07:15
User opened query 'Per CDM : Per IRT : subject was unblinded on 21JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:37:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:40

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'I'	System	22 Jan 2021 20:08:17



**US3822119**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'I'	System	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '62' in	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '140.2' lb	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '25.69653'	System	22 Jan 2021 20:11:22
DataPoint set to visible.	System	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '62' in	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '140.2' lb	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '25.69653'	System	22 Jan 2021 20:11:22
DataPoint set to visible.	System	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Jan 2021 20:11:22



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '11:21'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '22 Jan 2021 11:21'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '97.9' F	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '66'	(b) (4), (b) (6)	22 Jan 2021 20:11:22



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'bpm'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'breaths/min'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '117'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '76'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

**US3822119**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '62' in	(b) (4), (b) (6)	22 Jan 2021 20:11:22



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '140.2' lb	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '25.69653'	System	22 Jan 2021 20:11:22
DataPoint set to visible.	System	22 Jan 2021 20:08:17

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '12:44'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '22 Jan 2021 12:44'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '97.7' F	(b) (4), (b) (6)	22 Jan 2021 20:11:22



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '63'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

**US3822119**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'bpm'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'breaths/min'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '129'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	22 Jan 2021 20:11:22



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '76'	(b) (4), (b) (6)	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	22 Jan 2021 20:11:22

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:11:43

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:11:43

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mRNA-1273'	System	22 Jan 2021 20:12:06
DataPoint set to visible.	System	22 Jan 2021 20:08:17



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '11:51'	(b) (4), (b) (6)	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '22 Jan 2021 11:51'	System	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'ONCE'	System	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 20:12:06

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:12:20

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:12:20



US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '11:33'	(b) (4), (b) (6)	22 Jan 2021 20:12:20

**US3822119**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '22 Jan 2021 11:33'	System	22 Jan 2021 20:12:20

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:53:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:12:31

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:53:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:12:31

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:53:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '11:40'	(b) (4), (b) (6)	22 Jan 2021 20:12:31

**US3822119**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:53:40**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '22 Jan 2021 11:40'	System	22 Jan 2021 20:12:31

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:12:35

US3822119

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'I'	System	22 Jan 2021 20:12:35



US3822119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 14:57:16

US3822119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '29 Jan 2021'	(b) (4), (b) (6)	01 Feb 2021 14:57:16

US3822119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 14:57:16

US3822119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 14:57:16

US3822119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 14:57:24

**US3822119**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'I'	System	01 Feb 2021 14:57:24

**US3822119**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'I'	System	01 Feb 2021 14:57:24
DataPoint set to visible.	System	01 Feb 2021 14:57:24

US3822119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 20:26:05



US3822119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 20:26:05

US3822119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Feb 2021 20:26:05

**US3822119**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'OLD29'	System	26 Feb 2021 20:26:05

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '14:29'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '26 Feb 2021 14:29'	System	26 Feb 2021 20:27:39



US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:36:53
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 'Per PI, NCS' (Site from System).	(b) (4), (b) (6)	27 Feb 2021 14:02:58
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Feb 2021 20:27:39
User entered '96.4' F	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '77'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

**US3822119**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'bpm'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'breaths/min'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '123'	(b) (4), (b) (6)	26 Feb 2021 20:27:39



US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '71'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

**US3822119**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '15:20'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

**US3822119**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '26 Feb 2021 15:20'	System	26 Feb 2021 20:27:39



US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '97.6' F	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '71'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

**US3822119**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'bpm'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '17'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'breaths/min'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '137'	(b) (4), (b) (6)	26 Feb 2021 20:27:39



US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '72'	(b) (4), (b) (6)	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mmHg'	System	26 Feb 2021 20:27:39

US3822119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 20:28:09

US3822119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:28:09

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 20:28:26



US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'mRNA-1273'	System	26 Feb 2021 20:28:26
DataPoint set to visible.	System	01 Feb 2021 14:57:24

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '14:48'	(b) (4), (b) (6)	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '26 Feb 2021 14:48'	System	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	26 Feb 2021 20:29:41
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	26 Feb 2021 20:29:41
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 20:29:41
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	26 Feb 2021 20:28:26
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'ONCE'	System	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 20:28:26

US3822119

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 20:30:34



**US3822119**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'I'	System	26 Feb 2021 20:30:34

US3822119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 13:33:27

US3822119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:37:08
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety call is one day out of window, deviation noted' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 13:37:47
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Mar 2021 13:33:27
User entered '01 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 13:33:27

US3822119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Mar 2021 13:33:27

US3822119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:33:27

US3822119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 13:38:00

US3822119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'I'	System	03 Mar 2021 13:38:00

US3822119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 17:45:14



US3822119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 17:07:14
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Visit out of window. Deviation noted.' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 17:45:26
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Mar 2021 17:45:14
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 17:45:14

US3822119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 17:45:14

**US3822119**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered 'OLD57'	System	19 Mar 2021 17:45:14

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 17:45:51

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered empty.	System	19 Mar 2021 17:45:51

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51



US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered empty.	System	19 Mar 2021 17:45:51

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered empty.	System	19 Mar 2021 17:45:51

US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered empty.	System	19 Mar 2021 17:45:51



US3822119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:51

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered empty.	System	19 Mar 2021 17:45:51

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45

**US3822119**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45

US3822119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 17:45:54

US3822119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:45:54

US3822119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 17:46:07

US3822119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 17:46:07



**US3822119**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
User entered '10:40'	(b) (4), (b) (6)	19 Mar 2021 17:46:07

**US3822119**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:50:45
User entered '19 Mar 2021 10:40'	System	19 Mar 2021 17:46:07

US3822119

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:53:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:31:13
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES AND MUSCLE ACHES (DAY 8 on 24SEP2020) and FATIGUE (start date: Day 8; end date: Day 10) persist beyond Day 7 . Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:45:59
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES AND MUSCLE ACHES (DAY 8 on 24SEP2020) and FATIGUE (start date: Day 8; end date: Day 10) persist beyond Day 7 . Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'This was not due to vaccine, this was in relation to lupus and crohns disease per patient. please see crio for this. day 36 phone call sheet. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 16:23:07
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES AND MUSCLE ACHES (DAY 8 on 24SEP2020) and FATIGUE (start date: Day 8; end date: Day 10) persist beyond Day 7 . Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 08:40:38
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:20:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 18:38:03

US3822119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:40

[AEID](#)

Audit	User	Time (GMT)
User closed query 'Please separate UTI and Sepsis into two different AEs in CRIO. ' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	16 Nov 2020 03:19:07 10 Nov 2020 21:43:13
Query 'Please separate UTI and Sepsis into two different AEs in CRIO. ' answered with 'completed' (Site from CRA).	(b) (4) Kelly Woodell (b) (4)	10 Nov 2020 20:13:12
User opened query 'Please separate UTI and Sepsis into two different AEs in CRIO. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:30:36
User closed query 'Please ensure all data included in EDC is updated in CRIO.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:30:36
Query 'Please ensure all data included in EDC is updated in CRIO.' answered with 'UTI is listed in CRIO already on line 4' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:20:29
User opened query 'Please ensure all data included in EDC is updated in CRIO.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 19:44:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:20:35
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:36:49
User entered 'USA-US126-2020-mRNA-1273-P301000001'	System	11 Sep 2020 17:22:41
User entered 'New'	(b) (4), (b) (6)	11 Sep 2020 17:22:41

US3822119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:40

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:20:38
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:10:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:10:44
Data point term sent to Coder	System	10 Sep 2020 20:09:32
User entered 'Urinary Tract Infection'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:20:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:20:42
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:20:44
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50



US3822119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
	(b) (4)	
User closed query 'Per CRIO, start date is Sept. 3rd at 8:00pm. Please review and update EDC if applicable. (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:51:53
	(b) (4), (b) (6)	21 Oct 2020 15:51:46
Query 'Per CRIO, start date is Sept. 3rd at 8:00pm. Please review and update EDC if applicable.' answered with 'Date corrected' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 21:14:34
	(b) (4), (b) (6)	09 Oct 2020 21:12:47
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 21:12:47
User opened query 'Per CRIO, start date is Sept. 3rd at 8:00pm. Please review and update EDC if applicable.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:40:29
	(b) (4), (b) (6)	22 Sep 2020 14:21:03
User entered '04 Sep 2020'	Kelly Woodell (b) (4)	10 Sep 2020 20:08:50
	(b) (4)	

US3822119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
User closed query 'Per CDM Requery: Per previous query response "Updated"; however, the update is not obvious update data accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:53:52
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 14:53:50
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:48
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Keep getting queires saying to add then remove time. what do I do?' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 13:12:46
Query 'Per CDM Requery: Per previous query response "Updated"; however, the update is not obvious update data accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:11:44
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	23 Nov 2020 13:11:29
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 13:11:29
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 13:11:29
User entered '08:00' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:11:29
User closed query 'Please review and if applicable, update Start Time to 8:00am as noted in source.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:19:18
User opened query 'Per CDM Requery: Per previous query response "Updated"; however, the update is not obvious update data accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:12:03
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Nov 2020 16:28:33

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Kelly Woodell (b) (4)	04 Nov 2020 16:28:33
Query 'Please review and if applicable, update Start Time to 8:00am as noted in source.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	04 Nov 2020 16:21:17
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Nov 2020 16:20:48
DataPoint Un-verified.	Kelly Woodell (b) (4)	04 Nov 2020 16:20:48
User entered '08:00' reason for change: Data Entry Error	Kelly Woodell (b) (4)	04 Nov 2020 16:20:48
User opened query 'Please review and if applicable, update Start Time to 8:00am as noted in source.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:51:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:21:10
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 20:08:50

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 08:00'	System	23 Nov 2020 13:11:29
User entered empty.	System	04 Nov 2020 16:28:33
User entered '03 Sep 2020 08:00'	System	04 Nov 2020 16:20:48
User entered empty.	System	10 Sep 2020 20:08:50

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:52:07
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 21:12:47
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 14:21:17
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:21:12
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 20:08:50
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:52:09
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Oct 2020 16:33:48
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	14 Oct 2020 16:33:48
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Oct 2020 21:12:47
User entered '06 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 21:12:47
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CRIO, End Date is Sept. 6th. Please review and update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:19:31
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:52:14
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Oct 2020 16:34:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Oct 2020 16:34:35
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	14 Oct 2020 16:34:35
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'updated ' (Site from System).	Krishna Shah (b) (4) (b) (4)	14 Oct 2020 16:34:18
Query 'Per CRIO, End Date is Sept. 6th. Please review and update EDC if applicable.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	14 Oct 2020 16:34:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Oct 2020 21:12:47
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Oct 2020 21:12:47
User entered 'UK:UK' (non-conformant).	(b) (4), (b) (6)	09 Oct 2020 21:12:47
User opened query 'Per CRIO, End Date is Sept. 6th. Please review and update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 19:41:17
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 17:16:19
User entered empty.	System	14 Oct 2020 16:34:35
User entered '06 Sep 2020 UK:UK' (non-conformant).	System	09 Oct 2020 21:12:47
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 17:49:17
User entered empty.	System	10 Sep 2020 20:08:50



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[Severity](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:51:00
Query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' answered with 'Per PI the intensity was severe' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:13:08
User opened query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:22:58
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:54:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:55:30
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User closed query 'PV Query: Please clarify why subject required hospital admission for urinary tract infection (i.e failed outpatient therapy, signs of sepsis [fever, hypotension], etc.).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:07:14
Query 'PV Query: Please clarify why subject required hospital admission for urinary tract infection (i.e failed outpatient therapy, signs of sepsis [fever, hypotension], etc.).' answered with 'signs of sepsis' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:21:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User opened query 'PV Query: Please clarify why subject required hospital admission for urinary tract infection (i.e failed outpatient therapy, signs of sepsis [fever, hypotension], etc.).' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 17:50:04
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '04 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '06 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50



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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User closed query 'PV Query: Please confirm that subject will be receiving 2nd dose of study drug. If not, please update action taken accordingly. If so, please provide date the subject received study drug.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:07:06
Query 'PV Query: Please confirm that subject will be receiving 2nd dose of study drug. If not, please update action taken accordingly. If so, please provide date the subject received study drug.' answered with '2nd dose of study drug was administered' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:22:32
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User opened query 'PV Query: Please confirm that subject will be receiving 2nd dose of study drug. If not, please update action taken accordingly. If so, please provide date the subject received study drug.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 17:50:19
User entered 'Dose Delayed (DOSE DELAYED)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50



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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 18:51:31
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 17:48:59
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:31:56
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	14 Oct 2020 16:35:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Krishna Shah (b) (4) (b) (4)	14 Oct 2020 16:33:48
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 17:49:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:08:50

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory tests results (UA, urine culture, blood cultures, WBC, etc.). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 15:51:00
Query 'PV Query: Please provide any relevant laboratory tests results (UA, urine culture, blood cultures, WBC, etc.). Please include units and reference ranges if applicable.' answered with 'unable to get lab records from outside facility. ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 21:13:35
User closed query 'PV Query: Please confirm if diagnosis of sepsis was confirmed, and if so, how was it diagnosed? If diagnosed, please consider updating event term to urosepsis.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:51:10
Query 'PV Query: Please confirm if diagnosis of sepsis was confirmed, and if so, how was it diagnosed? If diagnosed, please consider updating event term to urosepsis.' answered with 'sepsis was confirmed and AE of Sepsis was added to the AE log. Please see log for further information. ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	23 Nov 2020 17:44:23
User opened query 'PV Query: Please confirm if diagnosis of sepsis was confirmed, and if so, how was it diagnosed? If diagnosed, please consider updating event term to urosepsis.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:23:15
User opened query 'PV Query: Please provide any relevant laboratory tests results (UA, urine culture, blood cultures, WBC, etc.). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:22:44
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User closed query 'PV Query: Please provide any relevant laboratory tests results (UA, urine culture, blood cultures, WBC, etc.). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:07:00
User closed query 'PV Query: Please provide dates for concomitant medications reported.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:06:52
Query 'PV Query: Please provide dates for concomitant medications reported.' answered with 'Concomitant medication date is listed on con med log' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:29:53

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory tests results (UA, urine culture, blood cultures, WBC, etc.). Please include units and reference ranges if applicable.' answered with 'Records will need to be requested to confirm. All that was received was the subjects discharge instructions.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:28:14
User opened query 'PV Query: Please provide dates for concomitant medications reported.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:25:55
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User opened query 'PV Query: Please provide any relevant laboratory tests results (UA, urine culture, blood cultures, WBC, etc.). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 17:49:50
User entered 'The patient went to the ER and was admitted for a urinary tract infection. She was given levofloxacin 500 mg QD x 5 days. She was released on 9/6/2020.'	Kelly Woodell (b) (4)	10 Sep 2020 20:08:50

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 20:08:50

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 20:08:50



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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 20:08:50

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**Form: Adverse Events (2)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:54
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User coded data point as SOC: Psychiatric disorders, HLT: Mental disorders NEC, PT: Mental status changes, LLT: Mental status changes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:20:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:20:41
Data point term sent to Coder	System	10 Sep 2020 20:11:39
User entered 'altered mental status due to sepsis'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:56
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:58
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:02
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:03
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '04 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User closed query 'Please confirm if start time is 12:00 per CRIO. Please reconcile and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:20:00
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
Query 'Please confirm if start time is 12:00 per CRIO. Please reconcile and update as applicable.' answered with 'Start time is not required if AE did not happen within 24 hours of dosing' (Site from CRA).	(b) (4) Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:25:18
User opened query 'Please confirm if start time is 12:00 per CRIO. Please reconcile and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:27:34
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21



**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User entered empty.	System	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:08
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '06 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User entered empty.	System	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 20:11:21



US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:17
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:19
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:20
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:24
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 20:11:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:27
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:28
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

US3822119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:30
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:01:56
User closed query 'Per CDM Re-query: Site response noted, however 'Relationship to investigational product' is required. Hence please update and then route back to DM.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:00:22
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
Query 'Per CDM Re-query: Site response noted, however 'Relationship to investigational product' is required. Hence please update and then route back to DM.' answered with 'not related to injection' (Site from DM).	(b) (4) Christina Kennelly (b) (4)	10 Nov 2020 21:41:21
DataPoint Un-verified.	Christina Kennelly (b) (4)	10 Nov 2020 21:39:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4) Christina Kennelly (b) (4)	10 Nov 2020 21:39:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:34
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User opened query 'Per CDM Re-query: Site response noted, however 'Relationship to investigational product' is required. Hence please update and then route back to DM.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:52:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 06:47:45
Query 'Data is required. Please complete.' answered with 'Will update once PI assess' (Site from System).	Kelly Woodell (b) (4)	10 Sep 2020 20:11:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Sep 2020 20:11:21
	Kelly Woodell (b) (4)	10 Sep 2020 20:11:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:36
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:38
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'None (NONE)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'I'	Kelly Woodell (b) (4)	10 Sep 2020 20:11:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:42
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:14:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:14:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:14:05
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:11:21
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:46
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 20:11:21

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:50
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:11:21

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User entered '0'	System	10 Sep 2020 20:11:21

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47
User entered 'I'	System	10 Sep 2020 20:11:21

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:47

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User closed query 'Per MM, please review and confirm if the seriousness of the event is correct.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:42:08
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
Query 'Per MM, please review and confirm if the seriousness of the event is correct.' answered with 'Seriousness is correct' (Site from DM).	Kelly Woodell (b) (4)	10 Nov 2020 20:17:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User opened query 'Per MM, please review and confirm if the seriousness of the event is correct.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:35:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 20:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 20:13:40
Data point term sent to Coder	System	10 Sep 2020 20:12:43
User entered 'Sepsis'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:06
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07



US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:12
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '04 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:15
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User entered empty.	System	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:02:09
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 10:31:12
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:36:38
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:36:30
Signature has been broken.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:36:30
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:36:30
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:34:11
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:17
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:02:12
DataPoint Un-verified.	Krishna Shah (b) (4)	23 Dec 2020 19:36:30
Signature has been broken.	(b) (4) Krishna Shah (b) (4)	23 Dec 2020 19:36:30
User entered '6 Sep 2020' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	23 Dec 2020 19:36:30
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:20
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07



**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User entered empty.	System	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:27
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:28
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:30
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:35
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07



US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:11:41
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:50
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:02:40
User closed query 'Per CDM Re-query: Site response noted, however 'Relationship to investigational product' is required. Hence please update and then route back to DM.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:59:45
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
Query 'Per CDM Re-query: Site response noted, however 'Relationship to investigational product' is required. Hence please update and then route back to DM.' answered with 'not related to injection' (Site from DM).	(b) (4) Christina Kennelly (b) (4)	10 Nov 2020 21:41:09
DataPoint Un-verified.	(b) (4) Christina Kennelly (b) (4)	10 Nov 2020 21:40:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:40:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:47
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User opened query 'Per CDM Re-query: Site response noted, however 'Relationship to investigational product' is required. Hence please update and then route back to DM.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:53:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 06:52:55
Query 'Data is required. Please complete.' answered with 'Will be updated once PI assess' (Site from System).	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:30
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:12:07
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:43
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:02
User closed query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.1, if the subject diagnosed with 'Acute moderate or severe infection with or without fever at the time of dosing , the participant may be injected at a later date within the time window or discontinued from dosing'. (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:48:13
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
Query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.1, if the subject diagnosed with 'Acute moderate or severe infection with or without fever at the time of dosing , the participant may be injected at a later date within the time window or discontinued from dosing'.' answered with 'updated' (Site from DM).	Kelly Woodell (b) (4)	10 Nov 2020 20:23:54
DataPoint Un-verified.	Kelly Woodell (b) (4)	10 Nov 2020 20:23:48
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	10 Nov 2020 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:41
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User opened query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.1, if the subject diagnosed with 'Acute moderate or severe infection with or without fever at the time of dosing , the participant may be injected at a later date within the time window or discontinued from dosing'. (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:36:00
User entered 'None (NONE)'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07



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Folder: Adverse Events

Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:34
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:33
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

US3822119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:02:19
DataPoint Un-verified.	Krishna Shah (b) (4)	23 Dec 2020 19:36:30
Signature has been broken.	(b) (4) Krishna Shah (b) (4)	23 Dec 2020 19:36:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Krishna Shah (b) (4)	23 Dec 2020 19:36:30
User signature succeeded.	(b) (4)	
	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:29
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:13:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:13:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:13:34
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:12:07
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:12:07

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:28
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:26:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 16:10:24
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:01:56
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 20:12:07

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User entered '0'	System	10 Sep 2020 20:12:07

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57
User entered 'I'	System	10 Sep 2020 20:12:07



**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:09:57

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:25
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental pain and sensation disorders, PT: Toothache, LLT: Tooth pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Nov 2020 20:39:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:39:42
Data point term sent to Coder	System	10 Nov 2020 20:39:20
User entered 'Tooth pain'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:26
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:28
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:30
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:40:49
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:40:53
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38



**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User entered empty.	System	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:02:29
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 16:27:08
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:39:25
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:39:18
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:39:18
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:57:42
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:41
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:42:24
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 14:42:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:42:24
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:40:56
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	10 Nov 2020 21:43:13
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:02:31
DataPoint Un-verified.	Krishna Shah (b) (4)	23 Dec 2020 19:39:18
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	23 Dec 2020 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:39
User closed query 'Please reconcile Start Date and End Date with CRIO Source and update CRIO and EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:53:36
User closed query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 14:42:49
Query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Nov 2020 14:42:49
Query 'Please reconcile Start Date and End Date with CRIO Source and update CRIO and EDC as applicable.' answered with 'No end date is in crio' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 14:42:38
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 14:42:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:42:24
User opened query 'Please reconcile Start Date and End Date with CRIO Source and update CRIO and EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:26:31
User closed query 'Please ensure stop and start date in CRIO match EDC. Please reconcile and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:26:31
Query 'Please ensure stop and start date in CRIO match EDC. Please reconcile and update as applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:17:06
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 13:17:00

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Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:17:00
User opened query 'Please ensure stop and start date in CRIO match EDC. Please reconcile and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:44:36
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '23 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (b) (4)	10 Nov 2020 20:46:03
	(b) (4)	
User entered '22 Aug 2020'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:40:59
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User entered empty.	System	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:01
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:03
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38



**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:05
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:07
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:09
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:11
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:13
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:16
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:18
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:20
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:23
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:41:25
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:51
User closed query 'Data is required. Per CRIO source. PI notes Causality as "Not Related". Please reconcile and update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:53:48
Query 'Data is required. Per CRIO source. PI notes Causality as "Not Related". Please reconcile and update EDC or source as applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:17:16
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 13:17:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:17:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 15:12:59
User opened query 'Data is required. Per CRIO source. PI notes Causality as "Not Related". Please reconcile and update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:43:26
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
Query 'Data is required. Please complete.' answered with 'Will add when PI assess' (Site from System).	(b) (4) Kelly Woodell (b) (4)	10 Nov 2020 20:38:47
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	10 Nov 2020 20:38:38
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:54:13
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'not applicable' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:18:05
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:03:40
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:05:25
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:43:37
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'None (NONE)'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:43:40
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

US3822119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:43:43
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'l'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:43:45
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:02:37
DataPoint Un-verified.	Krishna Shah (b) (4)	23 Dec 2020 19:39:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:42:49
Signature has been broken.	(b) (4), (b) (6)	23 Nov 2020 14:42:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:42:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:43:47
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:38:38

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:43:48
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:43:51
User signature succeeded.	Christina Kennelly (b) (4)	10 Nov 2020 21:43:13
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User entered '0'	System	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01
User entered '0'	System	10 Nov 2020 20:38:38

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:10:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:20
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:29
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	18 Feb 2021 16:45:28
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	15 Feb 2021 18:34:39
' answered with 'No. Patient was not assessed for COVID. ' (Site from DM).		
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	15 Feb 2021 12:20:41
' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	30 Jan 2021 20:46:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Jan 2021 20:46:28
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 20:37:39
User entered 'Chronic Obstructive Pulmonary Disease Diagnosis'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:31
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:33
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:26
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:35
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:39
	(b) (4), (b) (6)	
User entered '19 Oct 2020'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:42
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:32
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:46
User closed query ' Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:45:42
Query ' Per MM, please provide the end date.' answered with 'This is a diagnosis so there is no end date.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:35:01
User opened query ' Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:20:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4) (b) (4)	10 Nov 2020 21:42:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:09:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:06:48
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:38:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 20:38:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 20:38:48
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:36:53
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	



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Generated On: 10 Jun 2021 09:53:40

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Generated On: 10 Jun 2021 09:53:40

None

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Generated On: 10 Jun 2021 09:53:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:36:53
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:38:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	



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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:36:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Jan 2021 20:34:35
DataPoint inactivated with code reason code Data not required.	Christina Kennelly (b) (4)	10 Nov 2020 21:42:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User closed query 'Unable to locate source in CRIO. Please update AE page.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:31:31
Query 'Unable to locate source in CRIO. Please update AE page.' answered with 'Please see progress notes. Added in CRIO med hx page as well.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 21:16:16
User opened query 'Unable to locate source in CRIO. Please update AE page.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:59:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	30 Jan 2021 20:32:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Jan 2021 20:32:30
Data point term sent to Coder	System	29 Jan 2021 20:34:35
User entered 'Asthma Diagnosis'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '19 Oct 2020'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42



**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42



US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42



US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

None

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 20:33:42

US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	29 Jan 2021 20:33:42



US3822119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:50:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 15:17:12
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:00:26
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:33:42

**US3822119**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:33:42

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:53:40

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:31:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User closed query 'Per DM CLR: Per Diary Dose 1 Day 6 (18AUG2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:04:41
Query 'Per DM CLR: Per Diary Dose 1 Day 6 (18AUG2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Patient did not report a headache during day8 phone call' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:56:19
User opened query 'Per DM CLR: Per Diary Dose 1 Day 6 (18AUG2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 10:03:57
User closed query 'Please answer Concomitant Medication Procedures with "Yes" or "No". If Yes, please update concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:09

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:53:40

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Conmeds in CRIO include, Eye Shot for Macular Degeneration, Ibuprofen, and Anora Inhaler. Please update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:05
User closed query 'Please update CRIO Source with All Medications listed in EDC. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:19:39
Query 'Please answer Concomitant Medication Procedures with "Yes" or "No". If Yes, please update concomitant procedures.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:23:30
Query 'Conmeds in CRIO include, Eye Shot for Macular Degeneration, Ibuprofen, and Anora Inhaler. Please update EDC if applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:20:42
Query 'Please update CRIO Source with All Medications listed in EDC. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:20:37
User opened query 'Please answer Concomitant Medication Procedures with "Yes" or "No". If Yes, please update concomitant procedures.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:50:50
User opened query 'Conmeds in CRIO include, Eye Shot for Macular Degeneration, Ibuprofen, and Anora Inhaler. Please update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:02:03
User opened query 'Please update CRIO Source with All Medications listed in EDC. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:15:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:13:13
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:00

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 07:20:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 07:20:41
Data point term sent to Coder	System	10 Sep 2020 20:10:35
User entered 'Levofloxacin'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Urinary tract infection'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '500'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:20:30
User closed query 'Please review and if applicable, update Start Date to 07SEP2020 as noted in source. Please confirm that CRIO is correct.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 13:20:27
Query 'Please review and if applicable, update Start Date to 07SEP2020 as noted in source. Please confirm that CRIO is correct.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	22 Oct 2020 17:20:24
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	22 Oct 2020 17:20:14
User entered '7 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	22 Oct 2020 17:20:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User opened query 'Please review and if applicable, update Start Date to 07SEP2020 as noted in source. Please confirm that CRIO is correct.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:17:29
User entered '06 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:20:48
User closed query 'Per CRIO Source, Stop Date is 11SEP2020. Please review and update if applicable. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 13:20:46
Query 'Per CRIO Source, Stop Date is 11SEP2020. Please review and update if applicable. ' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	22 Oct 2020 17:20:30
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	22 Oct 2020 17:20:14
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	22 Oct 2020 17:20:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User opened query 'Per CRIO Source, Stop Date is 11SEP2020. Please review and update if applicable. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:18:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:20:51
DataPoint Un-verified.	Krishna Shah (b) (4)	22 Oct 2020 17:20:14
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	22 Oct 2020 17:20:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User entered '1'	System	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User entered '1'	System	10 Sep 2020 20:09:56

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:38
User entered '804 (804)'	System	10 Sep 2020 20:09:56



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 11:55:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 11:55:58
Data point term sent to Coder	System	13 Oct 2020 11:28:44
User entered 'Omeprazole'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Acid reflux/GERD'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '20'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:28:35

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:28:35



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:28:35

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:28:35



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:28:35

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:28:35

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: ATROPINE;DIPHENOXYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:56:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:56:22
Data point term sent to Coder	System	13 Oct 2020 11:30:44
User entered 'Diphenoxylate-atropine'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Frequent diarrhea'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '2.5-0.025'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:30:38



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

US3822119

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:30:38

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:30:38



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 11:30:38

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 11:30:38

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 11:59:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 11:59:03
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 11:31:45
User entered 'Gabapentin'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'UNK'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '100'	(b) (4), (b) (6)	13 Oct 2020 11:31:37



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:31:37

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'three times daily (TID)'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:31:37



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:31:37

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:31:37

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS ACTING LOCALLY, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 14:58:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 14:58:41
Data point term sent to Coder	System	13 Oct 2020 11:33:45
User entered 'Budesonide'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:33:17



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Crohn's'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '3'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:33:17



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:33:17

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:33:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:33:17



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Dec 2020 16:17:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 16:17:48
Data point term sent to Coder	System	22 Dec 2020 16:17:18
Coding entries removed.	(b) (4), (b) (6)	22 Dec 2020 16:16:50
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 11:59:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 11:59:25
Data point term sent to Coder	System	13 Oct 2020 11:34:45
User entered 'Levothyroxine'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User closed query 'Per DM CLR: Please update the indication to reflect the type of THYROID DISEASE. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:05:04
Query 'Per DM CLR: Please update the indication to reflect the type of THYROID DISEASE. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:16:56
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 16:16:50
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 16:16:50
User opened query 'Per DM CLR: Please update the indication to reflect the type of THYROID DISEASE. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 17:48:19
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Thyroid disease'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
Reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	27 Nov 2020 17:48:27
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '112'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'ug (ug)'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:34:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:34:20



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

US3822119

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:34:20



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:34:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:34:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE, PRODUCTSYNONYM: PRESERVISION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:18:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:18:16
Data point term sent to Coder	System	13 Oct 2020 11:35:46
User entered 'Preser Vision'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Eye health'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:35:14



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:35:14



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:35:14

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:35:14

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 11:59:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 11:59:57
Data point term sent to Coder	System	13 Oct 2020 11:36:46
User entered 'Sertraline'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'UNK'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '50'	(b) (4), (b) (6)	13 Oct 2020 11:36:15



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:36:15

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:36:15



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:36:15

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:36:15

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: SOLIFENACIN SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 06:44:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 06:44:32
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 11:37:48
User entered 'Selifenacin Succinate'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:37:28



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:07:04
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' answered with 'updated med hx' (Site from DM).	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:43:49
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 17:50:04
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Overactive bladder'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '10'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:28



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:37:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:37:28



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 20:54:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 20:54:00
Data point term sent to Coder DataPoint Un-verified.	System (b) (4), (b) (6)	26 Jan 2021 20:53:30 26 Jan 2021 20:52:41
Coding entries removed.	(b) (4), (b) (6)	26 Jan 2021 20:52:41
User entered 'LEVOCETIRIZINE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 20:52:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 19:43:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 19:43:42
Data point term sent to Coder	System	23 Dec 2020 19:42:32
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:42:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:28:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:28:01
Data point term sent to Coder	System	24 Nov 2020 20:26:43

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	24 Nov 2020 20:26:38
User entered 'Cetirizine' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:26:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:25:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:25:58
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' canceled (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:25:56
Data point term sent to Coder DataPoint Un-verified.	System (b) (4), (b) (6)	24 Nov 2020 20:24:40 24 Nov 2020 20:24:39
User entered 'Zyrtec' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:24:39
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 13:11:50
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
Data point term sent to Coder User entered 'OTC Allergy'	System (b) (4), (b) (6)	13 Oct 2020 11:38:49 13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

Indication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User closed query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:07:54
"		
' (Site from DM). Query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:42:16
"		
' answered with 'updated ' (Site from DM). DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:42:10
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:42:10
User opened query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	27 Nov 2020 17:50:42
"		
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Allergies'	(b) (4), (b) (6)	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (eg, 5, 10). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 14:23:35
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (eg, 5, 10). Please correct the dosage or provide explanation for alternate dosage.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 20:52:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 20:52:41
User entered '5' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 20:52:41
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (eg, 5, 10). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:48:34
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:44
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:24:39
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:24:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '25'	(b) (4), (b) (6)	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:37:50



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:37:50



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:37:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:37:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
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) (b) (4)	13 Oct 2020 12:00:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:22
Data point term sent to Coder	System	13 Oct 2020 11:38:49
User entered 'Probiotic'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	13 Oct 2020 11:38:16



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:16

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:16

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:38:16



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:16

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:38:16

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:38:16

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:29
Data point term sent to Coder	System	13 Oct 2020 11:39:50
User entered 'B-12'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:38:50



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '1500'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'ug (ug)'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:50



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:38:50

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:38:50

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 16:18:48
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)	13 Oct 2020 12:00:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 12:00:29
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 11:39:49
User entered 'Magnesium'	(b) (4), (b) (6)	13 Oct 2020 11:39:27



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '500'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:39:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:39:27



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:39:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:39:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:39:27



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:39:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;COLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:31
Data point term sent to Coder	System	13 Oct 2020 11:40:50
User entered 'Calcium + D3'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
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 using slash (e.g. 5/325). Also review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:10:09
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 using slash (e.g. 5/325). Also review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:41:31
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:41:22
User entered '1200/1000' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 19:41:22
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 using slash (e.g. 5/325). Also review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 17:51:30
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '1200'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
	(b) (4)	
DataPoint Un-verified.	Krishna Shah (b) (4)	23 Dec 2020 19:41:22
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Krishna Shah (b) (4)	23 Dec 2020 19:41:22
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
	(b) (4)	
DataPoint Un-verified.	Krishna Shah (b) (4)	23 Dec 2020 19:41:22
	(b) (4)	
User entered 'mg/IU' reason for change: Data Entry Error	Krishna Shah (b) (4)	23 Dec 2020 19:41:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:40:32



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:32

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:40:32

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:40:32



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:40:32

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:40:32

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:40:32

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 12:00:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 12:00:34
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 11:41:53
User entered 'Potassium'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '99'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:40:54



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:40:54



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:40:54

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:40:54

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:34
Data point term sent to Coder	System	13 Oct 2020 11:41:51
User entered 'Vitamin E'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:41:28



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '1000'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'IU (IU)'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

US3822119

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:28



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:41:28

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:41:28

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: PYRIDOXINE HYDROCHLORIDE, PRODUCTSYNONYM: B6 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:34
Data point term sent to Coder	System	13 Oct 2020 11:41:51
User entered 'B6'	(b) (4), (b) (6)	13 Oct 2020 11:41:47



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '100'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:47

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:41:47



US3822119

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:41:47

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 11:41:47



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 11:41:47

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
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: GLUCOSAMINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:39
Data point term sent to Coder	System	13 Oct 2020 11:43:53
User entered 'Glucosamine Sulfate'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Supplement'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '21,000'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	13 Oct 2020 11:43:20



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:43:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:43:20



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 11:43:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 11:43:20

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 11:43:20

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:47
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:23:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:23:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:40
Data point term sent to Coder User entered 'Influenza'	System (b) (4), (b) (6)	13 Oct 2020 11:44:53 13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Vaccine'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'unk'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Oct 2020 11:44:27



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un Sep 2019'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:44:27



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un Sep 2019'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User entered empty.	System	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User entered empty.	System	13 Oct 2020 11:44:27

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:33
User entered empty.	System	13 Oct 2020 11:44:27

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: POLIOMYELITIS VACCINES, PRODUCT: POLIO VACCINE, PRODUCTSYNONYM: POLIO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:40
Data point term sent to Coder	System	13 Oct 2020 11:44:54
User entered 'Polio'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Vaccine'	(b) (4), (b) (6)	13 Oct 2020 11:44:52



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'unk'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un UNK 1953'	(b) (4), (b) (6)	13 Oct 2020 11:44:52



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un UNK 1953'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User entered empty.	System	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User entered empty.	System	13 Oct 2020 11:44:52

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:35
User entered empty.	System	13 Oct 2020 11:44:52

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: MEASLES VACCINES, PRODUCT: MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE, PRODUCTSYNONYM: MMR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:01:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:01:07
Data point term sent to Coder	System	13 Oct 2020 11:45:54
User entered 'MMR'	(b) (4), (b) (6)	13 Oct 2020 11:45:17



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Vaccine'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'unk'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Oct 2020 11:45:17



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un UNK 1953'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un UNK 1953'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:45:17

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User entered empty.	System	13 Oct 2020 11:45:17

US3822119

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User entered empty.	System	13 Oct 2020 11:45:17



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:40
User entered empty.	System	13 Oct 2020 11:45:17

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:00:43
Data point term sent to Coder	System	13 Oct 2020 11:45:54
User entered 'Varicella'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Vaccine'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'unk'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:45:41

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Oct 2020 11:45:41



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un UNK 1953'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'un UNK 1953'	(b) (4), (b) (6)	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:18:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 11:45:41



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User entered empty.	System	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User entered empty.	System	13 Oct 2020 11:45:41

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:56:41
User entered empty.	System	13 Oct 2020 11:45:41

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:43:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:43:58
Data point term sent to Coder	System	10 Nov 2020 20:43:26
User entered 'Tylenol'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:36
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:39
User entered 'Tooth pain'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:41
User entered '500'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:44
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:51
User entered 'unknown (UNKNOWN)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:59:59
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:00:03
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:00:28
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:00:30
User entered '17 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:00:32
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:00:34
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:00:36
User entered '23 Aug 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	10 Nov 2020 20:47:39
User entered '22 Aug 2020'	(b) (4) Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:00:38
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User entered empty.	System	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User entered empty.	System	10 Nov 2020 20:43:19

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:54:45
User entered empty.	System	10 Nov 2020 20:43:19

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: ANORO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jan 2021 21:48:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:48:23
Data point term sent to Coder	System	29 Jan 2021 20:37:39
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 20:37:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:24:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: ANORO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:59:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:59:10
Data point term sent to Coder	System	23 Nov 2020 13:21:51
User entered 'Anora inhaler'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:11
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User closed query 'Per CDM re-query: Site response is noted that pt has Asthma with a medication start date of 20Oct and no MH of ASTHMA. According to CCGs pg.33, "Any abnormality after participant was dosed should be reported as an adverse event." Please confirm if the patient had Asthma BEFORE ICF was signed or if this was a new diagnosis. If new diagnosis, please add to AE eCRF. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:01:51
Query 'Per CDM re-query: Site response is noted that pt has Asthma with a medication start date of 20Oct and no MH of ASTHMA. According to CCGs pg.33, "Any abnormality after participant was dosed should be reported as an adverse event." Please confirm if the patient had Asthma BEFORE ICF was signed or if this was a new diagnosis. If new diagnosis, please add to AE eCRF. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 20:37:30
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 20:37:22
User entered 'ASTHMA, COPD' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 20:37:22
User opened query 'Per CDM re-query: Site response is noted that pt has Asthma with a medication start date of 20Oct and no MH of ASTHMA. According to CCGs pg.33, "Any abnormality after participant was dosed should be reported as an adverse event." Please confirm if the patient had Asthma BEFORE ICF was signed or if this was a new diagnosis. If new diagnosis, please add to AE eCRF. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:40:16
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:40:16



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Per source, pt has asthma' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 20:56:43
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:49:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:24:15
User entered 'Asthma'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:17
User entered '62.5/25'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:22
User entered 'ug (ug)'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 14:32:55
Reviewed for Data Management.	(b) (4), (b) (6)	27 Jan 2021 14:32:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:24:24
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:31
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:35
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:21:48



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:38
User entered '20 Oct 2020'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:42
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:47
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:21:48

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:24:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 13:21:48

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 13:21:48

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 13:21:48

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 13:21:48



US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 13:25:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 13:24:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 13:24:56
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 13:23:52
User entered 'Ibuprofen'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:25:54
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:12:18
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical condition added in MH on CRIO and in edc' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 13:47:26
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:50:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:25:56
User entered 'Hip pain'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:25:58
User entered '800'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:53:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:00
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:06
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:08
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:10
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:22:59



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:53:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:18
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:22
User entered '28 Sep 2020'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:24
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:53:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:28
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 13:22:59

US3822119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:53:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:26:30
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 13:22:59

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:53:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 13:22:59



**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 13:22:59

**US3822119**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:53:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 13:22:59

US3822119

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:53:40**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:58:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:54:21
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 13:23:22

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'USA-US126-2020-MRNA-1273-P301000001'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:51:15

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:51:15

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:20
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:15:54
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:41:05
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 13:33:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:44
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:42
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 13:19:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:36:45
	(b) (4), (b) (6)	

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:21
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:48
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:24
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'North Carolina' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:51
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 13:19:37



US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered '28083' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:54
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:59
User entered 'US' (non-conformant).	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 19:27:10
User entered '5'	System	24 Nov 2020 14:51:34
User entered '4'	System	05 Nov 2020 15:09:07
User entered '3'	System	15 Oct 2020 12:32:12
User entered '2'	System	12 Oct 2020 14:59:34
User entered '1'	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'USA-US126-2020-MRNA-1273-P301000001'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:51:15

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:51:15

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:20
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:15:54
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:41:05
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 13:33:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:44
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:42
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 13:19:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:36:45

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:21
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:48
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:24
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'North Carolina' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:51
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 13:19:37



US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered '28083' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:54
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:59
User entered 'US' (non-conformant).	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 19:27:10
User entered '5'	System	24 Nov 2020 14:51:34
User entered '4'	System	05 Nov 2020 15:09:07
User entered '3'	System	15 Oct 2020 12:32:12
User entered '2'	System	12 Oct 2020 14:59:34
User entered '1'	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:53:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
User entered '11/Sep/2020 13:37'	System	11 Sep 2020 17:37:24

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:53:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'USA-US126-2020-MRNA-1273-P301000001'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:51:15

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:51:15

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:20
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:15:54
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:41:05
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 13:33:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:44
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:42
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 13:19:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:36:45



US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:21
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:48
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:24
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'North Carolina' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:51
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered '28083' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:54
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:59
User entered 'US' (non-conformant).	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 19:27:10
User entered '5'	System	24 Nov 2020 14:51:34
User entered '4'	System	05 Nov 2020 15:09:07
User entered '3'	System	15 Oct 2020 12:32:12
User entered '2'	System	12 Oct 2020 14:59:34
User entered '1'	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:53:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:24:10
User entered '12/Oct/2020 14:59'	System	12 Oct 2020 14:59:34

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:53:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:24:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:32:03
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 14:59:34

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'USA-US126-2020-MRNA-1273-P301000001'	System	11 Sep 2020 17:22:41



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:51:15



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:51:15

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:20
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:15:54
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:41:05
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 13:33:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:44
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:42
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 13:19:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:36:45

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:21
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:48
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:24
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'North Carolina' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:51
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered '28083' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:54
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:59
User entered 'US' (non-conformant).	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 19:27:10
User entered '5'	System	24 Nov 2020 14:51:34
User entered '4'	System	05 Nov 2020 15:09:07
User entered '3'	System	15 Oct 2020 12:32:12
User entered '2'	System	12 Oct 2020 14:59:34
User entered '1'	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:53:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:24:33
User entered '15/Oct/2020 08:32'	System	15 Oct 2020 12:32:12



US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:53:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 15:08:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:24:35
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 12:32:12

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'USA-US126-2020-MRNA-1273-P301000001'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:51:15

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:51:15

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:20
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:15:54
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:41:05
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 13:33:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:44
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:42
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 13:19:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:36:45

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:21
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:48
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:24
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'North Carolina' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:51
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered '28083' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:54
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:59
User entered 'US' (non-conformant).	System	11 Sep 2020 17:37:24



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 19:27:10
User entered '5'	System	24 Nov 2020 14:51:34
User entered '4'	System	05 Nov 2020 15:09:07
User entered '3'	System	15 Oct 2020 12:32:12
User entered '2'	System	12 Oct 2020 14:59:34
User entered '1'	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:53:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:28:06
User entered '05/Nov/2020 15:09'	System	05 Nov 2020 15:09:07

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:53:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:28:06
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 15:09:07

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'USA-US126-2020-MRNA-1273-P301000001'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:51:15

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:51:15

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:20
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:15:54
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:41:05
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 13:33:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:44
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:42
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 13:19:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:36:45

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:21
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:48
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:24
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'North Carolina' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:51
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 13:19:37



US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered '28083' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:54
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:59
User entered 'US' (non-conformant).	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 19:27:10
User entered '5'	System	24 Nov 2020 14:51:34
User entered '4'	System	05 Nov 2020 15:09:07
User entered '3'	System	15 Oct 2020 12:32:12
User entered '2'	System	12 Oct 2020 14:59:34
User entered '1'	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:53:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:01:14
User entered '24/Nov/2020 14:51'	System	24 Nov 2020 14:51:34

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:53:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:01:16
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 14:51:34

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'USA-US126-2020-MRNA-1273-P301000001'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41



**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'Yes (Y)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 17:37:15
User entered 'No (N)'	System	11 Sep 2020 17:22:41

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:51:15

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:51:15

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:20
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:15:54
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:41:05
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 13:33:18
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:44
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:27:42
Query 'Please complete all address fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 13:19:37
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:36:45



US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:21
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:48
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:24
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered 'North Carolina' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:51
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:40

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:55:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:40:59
User entered '28083' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:40:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:26:54
Un-reviewed for Safety.	System	24 Nov 2020 14:51:34
DataPoint Un-verified.	System	24 Nov 2020 14:51:34
User entered empty.	System	24 Nov 2020 14:51:34
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:27:54
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 13:19:37

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:59:20
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:19:09
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:01:59
User entered 'US' (non-conformant).	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 19:27:10
User entered '5'	System	24 Nov 2020 14:51:34
User entered '4'	System	05 Nov 2020 15:09:07
User entered '3'	System	15 Oct 2020 12:32:12
User entered '2'	System	12 Oct 2020 14:59:34
User entered '1'	System	11 Sep 2020 17:37:24

**US3822119**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:53:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:01:25
User entered '24/Nov/2020 19:27'	System	24 Nov 2020 19:27:10

US3822119

Folder: SAE USA-US126-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:53:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:59:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:01:27
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 19:27:10