

US3302472 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:57:13

All time stamps listed in this document are displayed in GMT

US3302472

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:39:51

Generated On: 09 Jun 2021 16:57:13

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[Participant ID](#)

US3302472

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

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US3302472

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
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	False
Black	True
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) 19 Feb 2021 20:39:52

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	12 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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) 19 Feb 2021 20:39:52

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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) 19 Feb 2021 20:39:52

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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) 19 Feb 2021 20:39:52

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	CANDIDIASIS - ORAL
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	DEGENERATIVE DISC DISEASE
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	DIABETES MELLITUS - TYPE 2
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 (8)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	PARALYSIS - LEFT LEG
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	HEART ATTACK
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	EDEMA (BILATERAL UPPER AND LOWER EXTREMITIES)
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN OCT 1990
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 OCT 1990
Stop date completely unknown	False
Start Month and Year (derived)	OCT 1990
Start Year (derived)	1990
Stop Month and Year (derived)	OCT 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	DEFIBRILLATOR IMPLANT
Start date (dd MMM yyyy)	UN OCT 2019
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 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	CAD (CORONARY ARTERY DISEASE)
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Condition	CHEST PAIN - UNK
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	09:46 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:46
Height ( <i>xxx.x</i> )	63 in
Weight ( <i>xxx.x</i> )	147 lb
BMI ( <i>xxx.x</i> )	26.09433 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) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 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) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Date of assessment (dd MMM yyyy) 12 OCT 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 OCT 1990

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) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

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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** RETIRED

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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) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

<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) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

What was the date of randomization? (dd MMM yyyy) 12 OCT 2020

What was the participant's randomization number? 191288

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) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

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) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

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)	12 OCT 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:46
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	85 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 10:57
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

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) 12 OCT 2020

What was the treatment time? (00:00-23:59) 10:27 (24 HR)

Treatment Date and Time (derived) 12 OCT 2020 10:27

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) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

12 OCT 2020 09:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:53	12 OCT 2020 09:53
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:53

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Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 10:55

PC Open Date & Time

12 OCT 2020 10:47

PC Close Date & Time

12 OCT 2020 13:17

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**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 98.1 °F

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

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

PC Time Stamp	13 OCT 2020 07:36
PC Open Date & Time	12 OCT 2020 14:12
PC Close Date & Time	13 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

14 OCT 2020 05:16

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**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

97.8 °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

15 OCT 2020 06:45

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**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

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

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 12:21

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 16:56

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 13:52

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**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

12 OCT 2020 10:56

PC Open Date & Time

12 OCT 2020 10:47

PC Close Date & Time

12 OCT 2020 13:17

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**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

13 OCT 2020 07:37

PC Open Date & Time

12 OCT 2020 14:12

PC Close Date & Time

13 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**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

14 OCT 2020 05:17

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**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

15 OCT 2020 06:46

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**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

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**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

16 OCT 2020 12:21

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**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

17 OCT 2020 16:57

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**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

18 OCT 2020 13:52

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**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 ☐

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 10:57
PC Open Date & Time	12 OCT 2020 10:47
PC Close Date & Time	12 OCT 2020 13:17

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**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 ☐

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 07:38
PC Open Date & Time	12 OCT 2020 14:12
PC Close Date & Time	13 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**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 ☒

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 05:18
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**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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US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

		Yes <input type="checkbox"/>
PC Time stamp	15 OCT 2020 06:47	
PC Open Date & Time	14 OCT 2020 12:00	
PC Close Date & Time	15 OCT 2020 11:59	

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Yes ☐

PC Time stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**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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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 12:22
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 16:57
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 13:53
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3302472

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 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

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

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)	11 NOV 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 10:17
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

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)	11 NOV 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 11:57
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3302472

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

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) 11 NOV 2020

What was the treatment time? (00:00-23:59) 11:27 (24 HR)

Treatment Date and Time (derived) 11 NOV 2020 11:27

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

US3302472

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 NOV 2020
Collection time (00:00-23:59)	10:20 (24 HR)
Collection date and time (derived)	11 NOV 2020 10:20

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)			11 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:19	11 NOV 2020 10:19
Nasopharyngeal Swab 2	No		

US3302472

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 NOV 2020 11:48

PC Open Date & Time

11 NOV 2020 11:47

PC Close Date & Time

11 NOV 2020 14:17

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 NOV 2020 15:12

PC Close Date & Time

12 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**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

98.4 °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

12 NOV 2020 13:56

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 NOV 2020 13:27

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

14 NOV 2020 12:03

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 NOV 2020 13:13

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 NOV 2020 14:49

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 NOV 2020 12:27

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**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

11 NOV 2020 11:49

PC Open Date & Time

11 NOV 2020 11:47

PC Close Date & Time

11 NOV 2020 14:17

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**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

11 NOV 2020 15:12

PC Close Date & Time

12 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**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

12 NOV 2020 13:57

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**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

13 NOV 2020 13:28

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**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

14 NOV 2020 12:04

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**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

15 NOV 2020 13:13

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**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

16 NOV 2020 14:49

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**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

17 NOV 2020 12:27

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**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 ☐

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

No ☒

Yes ☐

PC Time stamp	11 NOV 2020 11:50
PC Open Date & Time	11 NOV 2020 11:47
PC Close Date & Time	11 NOV 2020 14:17

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**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 ☐

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 NOV 2020 15:12

PC Close Date & Time

12 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 3016

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	12 NOV 2020 13:58
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**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)

109 of 3016

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	13 NOV 2020 13:28
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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)

111 of 3016

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	14 NOV 2020 12:05
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 13:14
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	16 NOV 2020 14:50
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**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 ☒

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 12:28
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3302472

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 DEC 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

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 DEC 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	09 DEC 2020 09:55
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	93 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302472

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 DEC 2020

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

US3302472

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 DEC 2020

Collection time (00:00-23:59)

09:58 (24 HR)

Collection date and time (derived)

09 DEC 2020 09:58

US3302472

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:53

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 11:43:08
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 06:56:12
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 75
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	True
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 DEC 2020 09:53:36
Patient Cloud Open Date & Time	23 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 DEC 2020 09:29:29
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

06 JAN 2021 11:11:35

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 JAN 2021 11:47:58
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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

22 JAN 2021 12:03:06

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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	27 JAN 2021 04:17:53
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 02:55:11
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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	10 FEB 2021 00:02:24
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 04:57:49
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

<b>TIMEPOINT</b>	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 12:38:27
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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

03 MAR 2021 04:19:55

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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

10 MAR 2021 00:02:46

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 <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	17 MAR 2021 00:05:41
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 06:12:39
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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

31 MAR 2021 00:03:12

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 APR 2021 00:02:48
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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

14 APR 2021 05:15:59

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 APR 2021 04:33:18
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 03:53:34
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 <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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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°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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59
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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 397

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 <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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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28 AUG 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59
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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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06 NOV 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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"/>

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 NOV 2022 23:59

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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27 NOV 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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04 DEC 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

**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 ☐

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

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[Patient Cloud Close Date & Time](#)

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11 DEC 2022 23:59

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US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 DEC 2022 23:59

US3302472

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:57:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:33:42

US3302472

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:27:24

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

*If Contact Not Made, please provide Comments*

SITE ATTEMPTED TO CONTACT  
SUBJECT TO COMPLETE THEIR  
SAFETY CALL 85. SUBJECT  
DIDN'T RETURN PHONE CALL.

US3302472

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

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*

US3302472

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:27:24

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:27:24

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 12:39:14

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 12:39:14

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 APR 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 08:55
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302472

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 12:39:14

Generated On: 09 Jun 2021 16:57:13

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.*

US3302472

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 12:39:14

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 APR 2021

Collection time (00:00-23:59)

08:58 (24 HR)

Collection date and time (derived)

27 APR 2021 08:58

US3302472

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 12:39:14

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3302472**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

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*

**US3302472**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3302472

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Date of Contact	02 FEB 2021
Time of Contact	09:08
Date and Time of Contact (derived)	02 FEB 2021 09:08
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

US3302472

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	UNBLND_DECIDE

US3302472

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 16:09:00

Generated On: 09 Jun 2021 16:57:13

Date of updated informed consent ( <i>dd MMM yyyy</i> )	02 FEB 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> )	02 FEB 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

US3302472

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Height	
Weight	
BMI (xxx.x)	

US3302472

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 FEB 2021
Time of assessment (00:00-23:59)	09:13 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 09:13
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3302472

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 FEB 2021
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	02 FEB 2021 09:46
Temperature (xxx.x)	98.1 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3302472

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 FEB 2021

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

US3302472

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:39:51

Generated On: 09 Jun 2021 16:57:13

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) 02 FEB 2021

What was the treatment time? (00:00-23:59) 09:16 (24 HR)

Treatment Date and Time (derived) 02 FEB 2021 09:16

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

US3302472

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 FEB 2021

Collection time (00:00-23:59)

08:55 (24 HR)

Collection date and time (derived)

02 FEB 2021 08:55

US3302472

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:39:51

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	08:54
Collection Date and Time (derived)	02 FEB 2021 08:54

US3302472

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:51

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:39:52

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 19:03:43

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	OLD29

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 19:03:43

Generated On: 09 Jun 2021 16:57:13

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)	02 MAR 2021
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 08:49
Temperature (xxx.x)	98.0 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 19:03:43

Generated On: 09 Jun 2021 16:57:13

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)	02 MAR 2021
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 09:37
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3302472

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 19:03:43

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3302472

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 19:03:43

Generated On: 09 Jun 2021 16:57:13

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) 02 MAR 2021

What was the treatment time? (00:00-23:59) 09:07 (24 HR)

Treatment Date and Time (derived) 02 MAR 2021 09:07

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

US3302472

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 19:03:43

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:27:24

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3302472

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:27:24

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302472

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 16:09:00

Generated On: 09 Jun 2021 16:57:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 16:09:00

Generated On: 09 Jun 2021 16:57:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	30 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:32 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 08:32
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302472

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 16:09:00

Generated On: 09 Jun 2021 16:57:13

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.*

US3302472

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 16:09:00

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	08:34 (24 HR)
Collection date and time (derived)	30 MAR 2021 08:34

US3302472

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:39:51

Generated On: 09 Jun 2021 16:57:13

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3302472

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

AEID	USA-US087-2021-MRNA-1273-P30 1000017
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	22 DEC 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)	30 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	30 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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 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	

US3302472

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

---

SUBJECT REPORTS TO HER  
UNBLINDING VISIT TODAY  
AND STATED THAT SHE HAD  
BEEN HOSPITALIZED ON  
22DEC2020 AND DISCHARGED  
ON 30DEC2020 DU TO COVID-19.  
SUBJECT SIGNED MEDICAL  
RECORDS RELEASE FORM AND  
MEDICAL RECORDS HAVE  
BEEN REQUESTED. ONCE  
RECORDS ARE RECEIVED, SAE  
WILL BE UPDATED PER  
PROTOCOL.

4/5/2021:SUBJECT'S MEDICAL  
RECORDS REGARDING  
PREVIOUSLY REPORTED SAE  
HAS BEEN  
RECEIVED/REVIEWED. ALL  
CON MEDS, MEDICAL HISTORY,  
AND CON PROCEDURES LISTS  
UPDATED IN SOURCE AND EDC.  
IRB WAS UPDATED AFTER  
REVIEW.

---

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)	

---

---

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

AEID

Adverse event

ENDORSES ANOREXIA

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)

22 DEC 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 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

AEID

Adverse event

ACUTE RESPIRATORY FAILURE  
WITH HYPOXIA

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)

22 DEC 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 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

AEID

Adverse event

COPD EXACERBATION

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)

22 DEC 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 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:39:51

Generated On: 09 Jun 2021 16:57:13

---

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

Yes ☒

No ☐

---

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

---

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication ALBUTEROL (90MCG)

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication SYMBICORT

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 160/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication FARXIGA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication PROLIA

Prophylaxis Yes ☐  
No ☒

Indication OSTEOPOROSIS

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication EDEMA - BILATERAL UPPER  
AND LOWER EXTREMITIES

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication CORLANOR

Prophylaxis Yes ☐  
No ☒

Indication CHEST PAIN - UNK

Dose per administration 7.5

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 (6)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC	2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication CAD

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 (8)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC	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 (9)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication CRESTOR

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication ENTRESTO  
(SACUBITRIL/VALSARTAN)

Prophylaxis Yes ☐  
No ☒

Indication CAD (CORONARY ARTERY  
DISEASE)

Dose per administration 49/51

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication INJECTION 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 (11)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication O2

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 2

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

If dose unit is Other, specify LITERS

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

If frequency is Other, specify CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE

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)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication SODIUM CHLORIDE (0.9%  
BOLUS PREMIX)

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1,000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication ALBUTEROL NEBULIZER

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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

CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1,500

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 (17)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 600

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) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1,000

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 (19)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication IPRATROPIUM

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 1,000

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

CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication LACTATED RINGERS (INFUSION PREMIX)

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1,000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication IPRATROPIUM

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 1,000

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

CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 750

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

ONCE @ 125ML/ HOUR OVER  
120 MIN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication ALBUTEROL NEBULIZER  
(2.5MG/3ML)

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 1

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

If dose unit is Other, specify VIAL

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 DEC 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 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication REMDESIVIR

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE @ 500ML/HR OVER 30  
MIN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication ASCORBIC ACID

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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

Q 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication SODIUM CHLORIDE (0.9%  
INFUSION)

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1,000

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 (32)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication TUBERCULIN INJECTION

Prophylaxis Yes ☐  
No ☒

Indication TB SKIN TEST

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 (33)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication REMDESIVIR

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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

Q 24 HOURS VARIABLE @  
500ML/HR OVER 30 MIN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication EDEMA (BILATERAL UPPER  
AND LOWER EXTREMITIES)

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication ASCORBIC ACID

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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

Q 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication VITAMIN D3

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 5,000

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 (38)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 29 Apr 2021 12:39:13

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Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	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)	30 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication NICOTINE

Prophylaxis Yes ☐  
No ☒

Indication SMOKING CESSATION

Dose per administration 21/24

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

If dose unit is Other, specify MG/HR

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication DICLOFENAC

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify %

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication TROTROPIUM BROMIDE  
(25MCG)

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication CAD

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

Name of Medication PROAIR

Prophylaxis Yes ☐  
No ☒

Indication EMPHYSEMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 20:39:51

Generated On: 09 Jun 2021 16:57:13

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3302472

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:57:13

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

US3302472

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US087-2021-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US087-2021-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/FEB/2021 09:39
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

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US087-2021-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 19:00
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

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US087-2021-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 10:04
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

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 12:39:13

Generated On: 09 Jun 2021 16:57:13

SAEID	USA-US087-2021-MRNA-1273-P301000017
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	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 10:43
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

US3302472 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302472

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:57:13**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:43:12
Query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	23 Nov 2020 02:26:28
User opened query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:47:52
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:11:10
User entered 'US3302472'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 13:44:22

US3302472

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:11:33
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:05

US3302472

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:11:35
User entered '12 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 13:44:23

US3302472

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:11:36
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:05

US3302472

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'SCRN'	System	12 Oct 2020 14:30:05

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:06
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 13:44:25

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '71'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

**US3302472**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:57:13**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'YEARS'	System	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '71'	System	12 Oct 2020 14:30:30

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered 'Female (F)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered 'l'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:15:23
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:20

US3302472

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:33
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:30

US3302472

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Oct 2020'	System	12 Oct 2020 14:30:30

US3302472

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2020'	System	12 Oct 2020 14:30:30

US3302472

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 18:43:59
User closed query 'Please review the source and revise if needed. The site received Amendment#4 on 01-Oct-2020. The subject should have been enrolled under Amendment #4. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 18:43:56
Query 'Please review the source and revise if needed. The site received Amendment#4 on 01-Oct-2020. The subject should have been enrolled under Amendment #4. ' answered with 'done' (Site from CRA).	Brittany Belcher (b) (4)	23 Oct 2020 16:24:51
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 16:24:48
User opened query 'Please review the source and revise if needed. The site received Amendment#4 on 01-Oct-2020. The subject should have been enrolled under Amendment #4. ' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:17:23
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:30

US3302472

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:47
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:30

US3302472

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:49
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:30:30

US3302472

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:30:30

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:53
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:30

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:17:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 13:44:23

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'I'	System	12 Oct 2020 14:30:36

US3302472

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:57:13

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:22:23
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:36

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:57:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:25:27
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:41

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	Coder Import (b) (4)	16 Oct 2020 13:54:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Oct 2020 13:54:35
Data point term sent to Coder	System	16 Oct 2020 13:54:04
User closed query 'For coding purposes, please enter the type of ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' (Site from System).	System	16 Oct 2020 13:53:28
Query 'For coding purposes, please enter the type of ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' answered with 'updated ' (Site from System).	Wendy Taylor (b) (4)	16 Oct 2020 13:53:28
User entered 'Seasonal allergies' reason for change: Data Entry Error	Wendy Taylor (b) (4)	16 Oct 2020 13:53:21
User opened query 'For coding purposes, please enter the type of ALLERGIES (Seasonal, to food, to animals, to medications, multiple, etc) in order that the term may be coded accurately. Please make your changes to the reported term. (One type of allergy per line)' (Site from System).	Coder Import (b) (4)	15 Oct 2020 23:13:29
Data point term sent to Coder	System	12 Oct 2020 14:33:20
User entered 'allergy - unspecified'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:05

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 1970'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:05

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:05

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:05

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:33:05

US3302472

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:05

US3302472

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 1970'	System	12 Oct 2020 14:33:05

US3302472

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '1970'	System	12 Oct 2020 14:33:05

**US3302472**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:33:05

US3302472

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:33:05

US3302472

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Candida infections, PT: Oral candidiasis, LLT: Oral candidiasis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:58:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:58:19
Data point term sent to Coder	System	12 Oct 2020 14:34:20
User entered 'Candidiasis - Oral'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:26

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2018'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:26

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:26

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:26

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2018'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:26

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:33:26

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2018'	System	12 Oct 2020 14:33:26

US3302472

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2018'	System	12 Oct 2020 14:33:26

US3302472

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2018'	System	12 Oct 2020 14:33:26

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**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2018'	System	12 Oct 2020 14:33:26

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Bundle branch block left, LLT: Left bundle branch block - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 13:29:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 13:29:00
Data point term sent to Coder	System	12 Oct 2020 14:34:21
User entered 'Cardiac Arrhythmia - Left Bundle Branch Block'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:15

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2018'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2018'	System	12 Oct 2020 14:34:15

**US3302472**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2018'	System	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:34:15

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:23
Data point term sent to Coder	System	12 Oct 2020 14:35:21
User entered 'Degenerative Disc Disease'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 1984'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:33

**US3302472**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 1984'	System	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '1984'	System	12 Oct 2020 14:34:33

**US3302472**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:34:33

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:24
Data point term sent to Coder	System	12 Oct 2020 14:35:21
User entered 'Depression'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 1984'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 1984'	System	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '1984'	System	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:34:46

**US3302472**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:34:46

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:24
Data point term sent to Coder	System	12 Oct 2020 14:35:21
User entered 'Diabetes Mellitus - Type 2'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2003'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2003'	System	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2003'	System	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:04

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 10:47:19
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 17:08:00
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:27:03
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 14:36:24
Data point term sent to Coder	System	12 Oct 2020 14:35:22
User entered 'Emphysema'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2000'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2000'	System	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2000'	System	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:19

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:27
Data point term sent to Coder	System	12 Oct 2020 14:36:22
User entered 'Hypercholesterolemia'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2015'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2015'	System	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2015'	System	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:33

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:47:34
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Subject reports taking no medication for this condition. ' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 17:08:34
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:27:40
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:28
Data point term sent to Coder	System	12 Oct 2020 14:36:25
User entered 'Hypertension'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2016'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2016'	System	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2016'	System	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:35:45

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:28
Data point term sent to Coder	System	12 Oct 2020 14:36:25
User entered 'Osteoarthritis'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2008'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2008'	System	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:57:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2008'	System	12 Oct 2020 14:36:00

**US3302472**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:36:00

**US3302472**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:36:00

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:37:28
Data point term sent to Coder	System	12 Oct 2020 14:36:26
User entered 'Osteoporosis'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2008'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2008'	System	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2008'	System	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:36:16

**US3302472**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:36:16

US3302472

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Paralysis and paresis (excl cranial nerve), PT: Monoplegia, LLT: Paralysis leg - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 15:04:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 15:04:15
Data point term sent to Coder	System	12 Oct 2020 14:37:26
User entered 'Paralysis - left leg'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:44

US3302472

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 1984'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:44

US3302472

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:44

US3302472

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:44

US3302472

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 1984'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:44

US3302472

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:36:44

**US3302472**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 1984'	System	12 Oct 2020 14:36:44

**US3302472**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '1984'	System	12 Oct 2020 14:36:44

US3302472

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 1984'	System	12 Oct 2020 14:36:44

**US3302472**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '1984'	System	12 Oct 2020 14:36:44

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:38:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:38:17
Data point term sent to Coder	System	12 Oct 2020 14:37:28
User entered 'Heart Attack'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2019'	System	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:57:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2019'	System	12 Oct 2020 14:37:03

**US3302472**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2019'	System	12 Oct 2020 14:37:03

**US3302472**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2019'	System	12 Oct 2020 14:37:03

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Spasm muscle - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:38:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:38:16
Data point term sent to Coder	System	12 Oct 2020 14:37:27
User entered 'Spasm - Muscle'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2016'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2016'	System	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2016'	System	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:37:18

**US3302472**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:37:18

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of extremities - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:26:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:26:01
User closed query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:47:44
Query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 17:09:51
Data point term sent to Coder	System	29 Oct 2020 17:09:47
DataPoint Un-verified.	Brittany Belcher (b) (4)	29 Oct 2020 17:09:47
Coding entries removed.	Brittany Belcher (b) (4)	29 Oct 2020 17:09:47
User entered 'EDEMA (Bilateral Upper and lower Extremities)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 17:09:47
User opened query 'Per DM CLR: Please specify the location of Edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:28:22
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57

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Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:39:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:39:19
Data point term sent to Coder	System	12 Oct 2020 14:38:29
User entered 'edema'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2019'	System	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2019'	System	12 Oct 2020 14:37:30

**US3302472**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:37:30

**US3302472**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	12 Oct 2020 14:37:30

US3302472

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:43:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 19:43:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 19:43:37
Data point term sent to Coder	System	04 Nov 2020 19:42:55
DataPoint Un-verified.	brittany cooksey (b) (4)	04 Nov 2020 19:42:22
Coding entries removed.	brittany cooksey (b) (4)	04 Nov 2020 19:42:22
User entered 'bilateral TUBAL LIGATION' reason for change: Data Entry Error	brittany cooksey (b) (4)	04 Nov 2020 19:42:22
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 15:24:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 15:24:17
Data point term sent to Coder	System	12 Oct 2020 15:23:40
User entered 'Tubal Ligation'	Brittany Belcher (b) (4)	12 Oct 2020 15:23:07

US3302472

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un Oct 1990'	Brittany Belcher (b) (4)	12 Oct 2020 15:23:07

US3302472

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:23:07

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Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:23:07

US3302472

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered 'un Oct 1990'	Brittany Belcher (b) (4)	12 Oct 2020 15:23:07

US3302472

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:26:57
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:23:07

US3302472

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Oct 1990'	System	12 Oct 2020 15:23:07

**US3302472**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '1990'	System	12 Oct 2020 15:23:07

**US3302472**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Oct 1990'	System	12 Oct 2020 15:23:07

US3302472

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '1990'	System	12 Oct 2020 15:23:07

US3302472

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:43:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:04:35
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 15:04:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:33:33
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 14:33:33
Data point term sent to Coder	System	10 Nov 2020 14:33:07
User entered 'Defibrillator Implant'	Brittany Belcher (b) (4)	10 Nov 2020 14:32:19

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:43:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 14:32:34
User entered 'un Oct 2019' reason for change: Data Entry Error	Brittany Belcher (b) (4)	10 Nov 2020 14:32:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 14:32:19
User entered '00 Oct 2019' (non-conformant).	Brittany Belcher (b) (4)	10 Nov 2020 14:32:19

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:43:28
User entered '0'	Brittany Belcher (b) (4)	10 Nov 2020 14:32:19

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:43:32
User entered 'No (N)'	Brittany Belcher (b) (4)	10 Nov 2020 14:32:19

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:43:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 14:32:34
User entered 'un Oct 2019' reason for change: Data Entry Error	Brittany Belcher (b) (4)	10 Nov 2020 14:32:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 14:32:19
User entered '00 Oct 2019' (non-conformant).	Brittany Belcher (b) (4)	10 Nov 2020 14:32:19

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:43:37
User entered '0'	Brittany Belcher (b) (4)	10 Nov 2020 14:32:19

**US3302472**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Oct 2019'	System	10 Nov 2020 14:32:34
User entered empty.	System	10 Nov 2020 14:32:19

**US3302472**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2019'	System	10 Nov 2020 14:32:34
User entered empty.	System	10 Nov 2020 14:32:19

US3302472

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Oct 2019'	System	10 Nov 2020 14:32:34
User entered empty.	System	10 Nov 2020 14:32:19

**US3302472**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2019'	System	10 Nov 2020 14:32:34
User entered empty.	System	10 Nov 2020 14:32:19

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:19
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 16:13:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 16:13:32
Data point term sent to Coder	System	20 Nov 2020 13:07:23
User entered 'CAD (Coronary Artery Disease)'	Brittany Belcher (b) (4)	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:19
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:19
User entered '0'	Brittany Belcher (b) (4)	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:19
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:19
User entered empty.	Brittany Belcher (b) (4)	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:19
User entered '0'	Brittany Belcher (b) (4)	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2019'	System	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2019'	System	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:57:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	20 Nov 2020 13:06:52

US3302472

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:57:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 21:32:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 21:32:02
Data point term sent to Coder	System	25 Jan 2021 20:23:03
User entered 'Chest Pain - UNK'	brittany cooksey (b) (4)	25 Jan 2021 20:22:38

US3302472

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:23
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'un UNK 2019'	(b) (4) brittany cooksey (b) (4) (b) (4)	25 Jan 2021 20:22:38

US3302472

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:25
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	25 Jan 2021 20:22:38

US3302472

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4) brittany cooksey (b) (4) (b) (4)	25 Jan 2021 20:22:38

US3302472

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:57:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) brittany cooksey (b) (4) (b) (4)	25 Jan 2021 20:22:38

US3302472

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:25:33
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '0'	(b) (4) brittany cooksey (b) (4) (b) (4)	25 Jan 2021 20:22:38

**US3302472**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:57:13**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'Jan 2019'	System	25 Jan 2021 20:22:38

US3302472

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:57:13

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '2019'	System	25 Jan 2021 20:22:38

**US3302472**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	25 Jan 2021 20:22:38

**US3302472**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:57:13**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered empty.	System	25 Jan 2021 20:22:38

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered '09:46'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '12 Oct 2020 09:46'	System	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered '63' in	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10
DataPoint set to visible.	System	12 Oct 2020 14:30:36

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered '147' lb	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10
DataPoint set to visible.	System	12 Oct 2020 14:30:36

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered '26.09433'	System	12 Oct 2020 14:38:10
DataPoint set to visible.	System	12 Oct 2020 14:30:36

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'kg/m2'	System	12 Oct 2020 14:38:10
DataPoint set to visible.	System	12 Oct 2020 14:30:36

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	12 Oct 2020 14:38:33
User entered '97.9' F	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	12 Oct 2020 14:38:33
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	12 Oct 2020 14:38:33
User entered '74'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'bpm'	System	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	12 Oct 2020 14:38:33
User entered '18'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'breaths/min'	System	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	12 Oct 2020 14:38:33
User entered '85'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'mmHg'	System	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:32:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	12 Oct 2020 14:38:33
User entered '67'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User entered 'mmHg'	System	12 Oct 2020 14:38:10

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43

US3302472

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43

US3302472

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:33:27
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:42

US3302472

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:33:28
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 14:38:42

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:37:30
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:38:08
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:58:26
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	04 Nov 2020 19:42:34
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 16:37:32
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:38:10
User entered 'Surgically sterile (SURGICALLY STERILE)'	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:38:22
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:38:24
User entered 'un Oct 1990'	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:38:26
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:38:32
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:38:34
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:39:07

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered 'retired'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '0' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	03 Nov 2020 19:36:17
User entered '1'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 19:36:17
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '0'	(b) (4) Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:38:43
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:12
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:30:57

US3302472

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:39:52
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:31:07

US3302472

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:39:56
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 14:31:07

US3302472

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[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 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:39:56
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	12 Oct 2020 14:31:07

US3302472

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'VISIT1'	System	12 Oct 2020 14:31:07

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:45:39
User entered '12 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 14:03:45

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:45:39
User entered '191288'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 14:03:45

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:45:39
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 14:03:45

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:45:39
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:07

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:45:39
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:07

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:45:39
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 14:32:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 14:32:13
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	12 Oct 2020 14:32:13
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 14:32:07
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:32:07

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:45:39
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:07

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:45:39
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:07

US3302472

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:45:10
User entered 'No (N)'	Brittany Belcher (b) (4)	29 Oct 2020 14:49:45
DataPoint set to visible.	System	23 Oct 2020 16:24:48

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:54:48
User entered missing code ND - Not Done.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:54:51
User entered missing code ND - Not Done.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:54:48
User entered missing code ND - Not Done.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:54:51
User entered missing code ND - Not Done.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '09:46'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '12 Oct 2020 09:46'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '97.9' F	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '74'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'bpm'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '18'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'breaths/min'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '85'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '67'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:54:48
User entered missing code ND - Not Done.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:54:51
User entered missing code ND - Not Done.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '10:57'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '12 Oct 2020 10:57'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '97.9' F	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '67'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'bpm'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '18'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'breaths/min'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '107'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 16:56:29
User entered '77'	Brittany Belcher (b) (4)	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	12 Oct 2020 15:44:42

US3302472

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:24
User closed query 'Per eCRF Guidelines if screening and visit 1 are on the same day. The physical examination should be completed as no on this page. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:31:19
Query 'Per eCRF Guidelines if screening and visit 1 are on the same day. The physical examination should be completed as no on this page. ' answered with 'done' (Site from CRA).	Brittany Belcher (b) (4)	29 Oct 2020 14:49:59
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 14:49:54
User opened query 'Per eCRF Guidelines if screening and visit 1 are on the same day. The physical examination should be completed as no on this page. ' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 17:12:40
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:18

US3302472

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:24
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 14:49:54
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:18

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:31
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:31
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:31
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:31
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:31
User entered '10:27'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '12 Oct 2020 10:27'	System	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:31
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:31
User entered 'ONCE'	System	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 14:32:31

US3302472

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:48
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:32

US3302472

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:48
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:32

US3302472

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:13:48
User entered '09:55'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:32

US3302472

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '12 Oct 2020 09:55'	System	12 Oct 2020 15:50:32

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:48:12
User entered '12 Oct 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:14:27
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:14:29
User entered '09:53'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '12 Oct 2020 09:53'	System	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:46:39
DataPoint Un-verified.	Wendy Taylor (b) (4)	20 Oct 2020 17:35:39
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 17:35:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:14:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:46:43
DataPoint Un-verified.	Wendy Taylor (b) (4)	20 Oct 2020 17:35:39
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 17:35:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:14:53
User entered '09:53'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered empty.	System	20 Oct 2020 17:35:39
User entered '12 Oct 2020 09:53'	System	12 Oct 2020 15:50:46

US3302472

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:15:24
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:50:51

US3302472

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	12 Oct 2020 15:50:51

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:54:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1c4b55ac-723c-4d3b-bc32-34a75c3a1fc1'	System	12 Oct 2020 14:55:08
User entered 'Yes (Y)'	System	12 Oct 2020 14:55:08

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:54:28', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1c4b55ac-723c-4d3b-bc32-34a75c3a1fc1'	System	12 Oct 2020 14:55:08
User entered '97.9'	System	12 Oct 2020 14:55:08

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:54:38', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1c4b55ac-723c-4d3b-bc32-34a75c3a1fc1'	System	12 Oct 2020 14:55:08
User entered 'No (N)'	System	12 Oct 2020 14:55:08

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:55:03', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1c4b55ac-723c-4d3b-bc32-34a75c3a1fc1'	System	12 Oct 2020 14:55:08
User entered '12 Oct 2020 10:55'	System	12 Oct 2020 14:55:08

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 10:47'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 13:17'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:35:24', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0a7c0fb0-1ea1-415c-abae-6bde1f65d0f0'	System	13 Oct 2020 11:36:21
User entered 'Yes (Y)'	System	13 Oct 2020 11:36:21

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:35:42', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0a7c0fb0-1ea1-415c-abae-6bde1f65d0f0'	System	13 Oct 2020 11:36:21
User entered '98.1'	System	13 Oct 2020 11:36:21

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:35:52', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0a7c0fb0-1ea1-415c-abae-6bde1f65d0f0'	System	13 Oct 2020 11:36:21
User entered 'No (N)'	System	13 Oct 2020 11:36:21

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:36:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0a7c0fb0-1ea1-415c-abae-6bde1f65d0f0'	System	13 Oct 2020 11:36:21
User entered '13 Oct 2020 07:36'	System	13 Oct 2020 11:36:21

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 14:12'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 2'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:15:56', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0319d72e-ac0f-4d73-8b79-11660168e471'	System	14 Oct 2020 09:16:59
User entered 'Yes (Y)'	System	14 Oct 2020 09:16:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:16:13', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0319d72e-ac0f-4d73-8b79-11660168e471'	System	14 Oct 2020 09:16:59
User entered '97.1'	System	14 Oct 2020 09:16:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:16:21', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0319d72e-ac0f-4d73-8b79-11660168e471'	System	14 Oct 2020 09:16:59
User entered 'Yes (Y)'	System	14 Oct 2020 09:16:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
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 'done' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 15:46:56
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:16:43', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0319d72e-ac0f-4d73-8b79-11660168e471'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:28
User entered '1'	System	14 Oct 2020 09:16:59
	System	14 Oct 2020 09:16:59
	System	14 Oct 2020 09:16:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:16:43', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0319d72e-ac0f-4d73-8b79-11660168e471'	System	14 Oct 2020 09:16:59
User entered '0'	System	14 Oct 2020 09:16:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:16:56', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '0319d72e-ac0f-4d73-8b79-11660168e471'	System	14 Oct 2020 09:16:59
User entered '14 Oct 2020 05:16'	System	14 Oct 2020 09:16:59

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 3'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:45:22', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '8bf8bd15-ae3b-401a-94c1-0546bf147c1e'	System	15 Oct 2020 10:45:58
User entered 'Yes (Y)'	System	15 Oct 2020 10:45:58

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:45:38', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '8bf8bd15-ae3b-401a-94c1-0546bf147c1e'	System	15 Oct 2020 10:45:58
User entered '97.8'	System	15 Oct 2020 10:45:58

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:45:47', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '8bf8bd15-ae3b-401a-94c1-0546bf147c1e'	System	15 Oct 2020 10:45:58
User entered 'No (N)'	System	15 Oct 2020 10:45:58

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:45:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '8bf8bd15-ae3b-401a-94c1-0546bf147c1e'	System	15 Oct 2020 10:45:58
User entered '15 Oct 2020 06:45'	System	15 Oct 2020 10:45:58

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 4'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 5'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:20:56', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9b83fa44-5876-4cc8-9bea-2aa7157def87'	System	16 Oct 2020 16:21:29
User entered 'Yes (Y)'	System	16 Oct 2020 16:21:29

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:10', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9b83fa44-5876-4cc8-9bea-2aa7157def87'	System	16 Oct 2020 16:21:29
User entered '98.3'	System	16 Oct 2020 16:21:29

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:18', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9b83fa44-5876-4cc8-9bea-2aa7157def87'	System	16 Oct 2020 16:21:29
User entered 'No (N)'	System	16 Oct 2020 16:21:29

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:24', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9b83fa44-5876-4cc8-9bea-2aa7157def87'	System	16 Oct 2020 16:21:29
User entered '16 Oct 2020 12:21'	System	16 Oct 2020 16:21:29

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 6'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:56:03', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7d92474b-fe26-4a7d-a7ad-2bff789a2f67'	System	17 Oct 2020 20:56:35
User entered 'Yes (Y)'	System	17 Oct 2020 20:56:35

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:56:14', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7d92474b-fe26-4a7d-a7ad-2bff789a2f67'	System	17 Oct 2020 20:56:35
User entered '98.3'	System	17 Oct 2020 20:56:35

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:56:25', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7d92474b-fe26-4a7d-a7ad-2bff789a2f67'	System	17 Oct 2020 20:56:35
User entered 'No (N)'	System	17 Oct 2020 20:56:35

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:56:32', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7d92474b-fe26-4a7d-a7ad-2bff789a2f67'	System	17 Oct 2020 20:56:35
User entered '17 Oct 2020 16:56'	System	17 Oct 2020 20:56:35

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 7'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:51:34', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'f8e7e681-40bb-41ff-bcbd-0a81d6b5db3c'	System	18 Oct 2020 17:52:12
User entered 'Yes (Y)'	System	18 Oct 2020 17:52:12

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:51:57', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'f8e7e681-40bb-41ff-bcbd-0a81d6b5db3c'	System	18 Oct 2020 17:52:12
User entered '97.3'	System	18 Oct 2020 17:52:12

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:03', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'f8e7e681-40bb-41ff-bcbd-0a81d6b5db3c'	System	18 Oct 2020 17:52:12
User entered 'No (N)'	System	18 Oct 2020 17:52:12

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:10', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'f8e7e681-40bb-41ff-bcbd-0a81d6b5db3c'	System	18 Oct 2020 17:52:12
User entered '18 Oct 2020 13:52'	System	18 Oct 2020 17:52:12

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:56:20', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b305e140-28b1-46e0-9190-f90ccc1b85f9'	System	12 Oct 2020 14:56:47
User entered 'None (1)'	System	12 Oct 2020 14:56:47

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:56:25', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b305e140-28b1-46e0-9190-f90ccc1b85f9'	System	12 Oct 2020 14:56:47
User entered 'No (N)'	System	12 Oct 2020 14:56:47

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:56:31', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b305e140-28b1-46e0-9190-f90ccc1b85f9'	System	12 Oct 2020 14:56:47
User entered 'No (N)'	System	12 Oct 2020 14:56:47

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:56:37', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b305e140-28b1-46e0-9190-f90ccc1b85f9'	System	12 Oct 2020 14:56:47
User entered 'None (1)'	System	12 Oct 2020 14:56:47

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:56:44', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b305e140-28b1-46e0-9190-f90ccc1b85f9'	System	12 Oct 2020 14:56:47
User entered '12 Oct 2020 10:56'	System	12 Oct 2020 14:56:47

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 10:47'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 13:17'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:36:46', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3593eda8-ba07-4248-aa44-266912d115b8'	System	13 Oct 2020 11:37:38
User entered 'None (1)'	System	13 Oct 2020 11:37:38

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:36:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3593eda8-ba07-4248-aa44-266912d115b8'	System	13 Oct 2020 11:37:38
User entered 'No (N)'	System	13 Oct 2020 11:37:38

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:37:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3593eda8-ba07-4248-aa44-266912d115b8'	System	13 Oct 2020 11:37:38
User entered 'No (N)'	System	13 Oct 2020 11:37:38

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:37:10', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3593eda8-ba07-4248-aa44-266912d115b8'	System	13 Oct 2020 11:37:38
User entered 'None (1)'	System	13 Oct 2020 11:37:38

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:37:36', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3593eda8-ba07-4248-aa44-266912d115b8'	System	13 Oct 2020 11:37:38
User entered '13 Oct 2020 07:37'	System	13 Oct 2020 11:37:38

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 14:12'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 2'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:17:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '86cc6426-c06a-4c99-be1d-cc63d7c69903'	System	14 Oct 2020 09:17:42
User entered 'None (1)'	System	14 Oct 2020 09:17:42

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:17:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '86cc6426-c06a-4c99-be1d-cc63d7c69903'	System	14 Oct 2020 09:17:42
User entered 'No (N)'	System	14 Oct 2020 09:17:42

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:17:23', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '86cc6426-c06a-4c99-be1d-cc63d7c69903'	System	14 Oct 2020 09:17:42
User entered 'No (N)'	System	14 Oct 2020 09:17:42

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:17:29', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '86cc6426-c06a-4c99-be1d-cc63d7c69903'	System	14 Oct 2020 09:17:42
User entered 'None (1)'	System	14 Oct 2020 09:17:42

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:17:41', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '86cc6426-c06a-4c99-be1d-cc63d7c69903'	System	14 Oct 2020 09:17:42
User entered '14 Oct 2020 05:17'	System	14 Oct 2020 09:17:42

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 3'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:06', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9bfc1a89-4fb7-4d68-9de9-a5990a967979'	System	15 Oct 2020 10:46:33
User entered 'None (1)'	System	15 Oct 2020 10:46:33

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:11', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9bfc1a89-4fb7-4d68-9de9-a5990a967979'	System	15 Oct 2020 10:46:33
User entered 'No (N)'	System	15 Oct 2020 10:46:33

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9bfc1a89-4fb7-4d68-9de9-a5990a967979'	System	15 Oct 2020 10:46:33
User entered 'No (N)'	System	15 Oct 2020 10:46:33

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:24', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9bfc1a89-4fb7-4d68-9de9-a5990a967979'	System	15 Oct 2020 10:46:33
User entered 'None (1)'	System	15 Oct 2020 10:46:33

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:28', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9bfc1a89-4fb7-4d68-9de9-a5990a967979'	System	15 Oct 2020 10:46:33
User entered '15 Oct 2020 06:46'	System	15 Oct 2020 10:46:33

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 4'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 5'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:31', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b32e45ae-a843-46aa-a8ea-313300de15f9'	System	16 Oct 2020 16:21:57
User entered 'None (1)'	System	16 Oct 2020 16:21:57

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:37', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b32e45ae-a843-46aa-a8ea-313300de15f9'	System	16 Oct 2020 16:21:57
User entered 'No (N)'	System	16 Oct 2020 16:21:57

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:43', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b32e45ae-a843-46aa-a8ea-313300de15f9'	System	16 Oct 2020 16:21:57
User entered 'No (N)'	System	16 Oct 2020 16:21:57

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:48', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b32e45ae-a843-46aa-a8ea-313300de15f9'	System	16 Oct 2020 16:21:57
User entered 'None (1)'	System	16 Oct 2020 16:21:57

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:21:52', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b32e45ae-a843-46aa-a8ea-313300de15f9'	System	16 Oct 2020 16:21:57
User entered '16 Oct 2020 12:21'	System	16 Oct 2020 16:21:57

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 6'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:56:48', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '626643e5-69be-4553-bd75-d98ef905a75f'	System	17 Oct 2020 20:57:14
User entered 'None (1)'	System	17 Oct 2020 20:57:14

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:56:53', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '626643e5-69be-4553-bd75-d98ef905a75f'	System	17 Oct 2020 20:57:14
User entered 'No (N)'	System	17 Oct 2020 20:57:14

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:56:58', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '626643e5-69be-4553-bd75-d98ef905a75f'	System	17 Oct 2020 20:57:14
User entered 'No (N)'	System	17 Oct 2020 20:57:14

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:03', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '626643e5-69be-4553-bd75-d98ef905a75f'	System	17 Oct 2020 20:57:14
User entered 'None (1)'	System	17 Oct 2020 20:57:14

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:09', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '626643e5-69be-4553-bd75-d98ef905a75f'	System	17 Oct 2020 20:57:14
User entered '17 Oct 2020 16:57'	System	17 Oct 2020 20:57:14

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 7'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:18', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e248f42e-35e7-4d49-9c33-d878d5875662'	System	18 Oct 2020 17:52:46
User entered 'None (1)'	System	18 Oct 2020 17:52:46

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:23', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e248f42e-35e7-4d49-9c33-d878d5875662'	System	18 Oct 2020 17:52:46
User entered 'No (N)'	System	18 Oct 2020 17:52:46

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:27', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e248f42e-35e7-4d49-9c33-d878d5875662'	System	18 Oct 2020 17:52:46
User entered 'No (N)'	System	18 Oct 2020 17:52:46

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:32', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e248f42e-35e7-4d49-9c33-d878d5875662'	System	18 Oct 2020 17:52:46
User entered 'None (1)'	System	18 Oct 2020 17:52:46

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:44', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e248f42e-35e7-4d49-9c33-d878d5875662'	System	18 Oct 2020 17:52:46
User entered '18 Oct 2020 13:52'	System	18 Oct 2020 17:52:46

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:56:59', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered 'None (0)'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:57:02', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered 'None (0)'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:57:07', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered 'None (0)'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:57:12', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered 'None (0)'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:57:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered 'None (0)'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:57:23', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered 'None (0)'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:57:35', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered 'No (N)'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-12T10:57:49', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '42e68177-d693-4c90-8584-2f5dbf9669d4'	System	12 Oct 2020 14:57:53
User entered '12 Oct 2020 10:57'	System	12 Oct 2020 14:57:53

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 10:47'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 13:17'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:37:43', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered 'None (0)'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:37:50', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered 'None (0)'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:37:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered 'None (0)'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:37:59', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered 'None (0)'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:38:02', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered 'None (0)'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:38:10', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered 'None (0)'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:38:23', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered 'No (N)'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-13T07:38:33', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c35d5f14-f042-44b7-9759-272a145e3da1'	System	13 Oct 2020 11:38:38
User entered '13 Oct 2020 07:38'	System	13 Oct 2020 11:38:38

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Oct 2020 14:12'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 2'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:18:42', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1'	System	14 Oct 2020 09:18:48
User entered 'None (0)'	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:17:58', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1'	System	14 Oct 2020 09:18:48
User entered 'None (0)'	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:18:04', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1' User entered 'None (0)'	System	14 Oct 2020 09:18:48
	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:18:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1' User entered 'None (0)'	System	14 Oct 2020 09:18:48
	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:18:14', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1' User entered 'None (0)'	System	14 Oct 2020 09:18:48
	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:18:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1'	System	14 Oct 2020 09:18:48
User entered 'None (0)'	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:18:26', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1'	System	14 Oct 2020 09:18:48
User entered 'No (N)'	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-14T05:18:47', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9c18f1d3-7328-4667-a640-9dd3152012a1' User entered '14 Oct 2020 05:18'	System	14 Oct 2020 09:18:48
	System	14 Oct 2020 09:18:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 3'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:36', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1'	System	15 Oct 2020 10:47:22
User entered 'None (0)'	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:42', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1'	System	15 Oct 2020 10:47:22
User entered 'None (0)'	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:46', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1'	System	15 Oct 2020 10:47:22
User entered 'None (0)'	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:51', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1'	System	15 Oct 2020 10:47:22
User entered 'None (0)'	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:46:58', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1'	System	15 Oct 2020 10:47:22
User entered 'None (0)'	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:47:02', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1'	System	15 Oct 2020 10:47:22
User entered 'None (0)'	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:47:11', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1'	System	15 Oct 2020 10:47:22
User entered 'No (N)'	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-15T06:47:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1e792c22-6d83-4c11-ab67-93e112fe5ac1' User entered '15 Oct 2020 06:47'	System	15 Oct 2020 10:47:22
	System	15 Oct 2020 10:47:22

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 4'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 5'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered 'None (0)'	System	16 Oct 2020 16:22:36

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:06', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered 'None (0)'	System	16 Oct 2020 16:22:36

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:11', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered 'None (0)'	System	16 Oct 2020 16:22:36

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered 'None (0)'	System	16 Oct 2020 16:22:36

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:21', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered 'None (0)'	System	16 Oct 2020 16:22:36

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:24', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered 'None (0)'	System	16 Oct 2020 16:22:36

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:29', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered 'No (N)'	System	16 Oct 2020 16:22:36

**US3302472**

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

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

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-16T12:22:31', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3a6fca60-42fd-4443-8db3-a48403de4b49'	System	16 Oct 2020 16:22:36
User entered '16 Oct 2020 12:22'	System	16 Oct 2020 16:22:36

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 6'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered 'None (0)'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:22', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered 'None (0)'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:26', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered 'None (0)'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:31', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered 'None (0)'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:35', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered 'None (0)'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:38', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered 'None (0)'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:45', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered 'No (N)'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-17T16:57:50', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a0593c2a-9c1d-45aa-b913-a9b2a8cf6b45'	System	17 Oct 2020 20:57:55
User entered '17 Oct 2020 16:57'	System	17 Oct 2020 20:57:55

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	12 Oct 2020 14:32:31
User entered 'Day 7'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:51', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered 'None (0)'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:52:59', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered 'None (0)'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:53:07', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered 'None (0)'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:53:12', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered 'None (0)'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:53:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered 'None (0)'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:53:23', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered 'None (0)'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:53:28', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered 'No (N)'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-10-18T13:53:33', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '44085b2b-57be-4060-98cd-3e5e8341f961'	System	18 Oct 2020 17:53:39
User entered '18 Oct 2020 13:53'	System	18 Oct 2020 17:53:39

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 14:32:31

US3302472

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 14:32:31

US3302472

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:18:12

US3302472

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:12
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 15:18:12

US3302472

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 15:18:12

US3302472

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:12
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 15:18:12

US3302472

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:18:15

US3302472

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	20 Oct 2020 15:18:15

US3302472

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:08
User entered 'Yes (Y)'	brittany cooksey (b) (4)	29 Oct 2020 20:59:34

US3302472

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:08
User entered '29 Oct 2020'	brittany cooksey (b) (4)	29 Oct 2020 20:59:34

US3302472

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:08
User entered 'Contact Made (CONTACT MADE)'	brittany cooksey (b) (4)	29 Oct 2020 20:59:34

US3302472

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:08
User entered empty.	brittany cooksey (b) (4)	29 Oct 2020 20:59:34

US3302472

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:14
User entered 'Yes (Y)'	brittany cooksey (b) (4)	29 Oct 2020 20:59:40

US3302472

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	29 Oct 2020 20:59:40

US3302472

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:42
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	02 Nov 2020 15:26:39

US3302472

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:42
User entered '2 Nov 2020'	Wendy Taylor (b) (4)	02 Nov 2020 15:26:39

US3302472

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:42
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	02 Nov 2020 15:26:39

US3302472

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:33:42
User entered empty.	Wendy Taylor (b) (4)	02 Nov 2020 15:26:39

US3302472

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:34:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:20:50

**US3302472**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	11 Nov 2020 15:20:50

US3302472

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:42:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:20:59

US3302472

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:42:53
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 15:20:59

US3302472

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[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 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:42:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 15:20:59

US3302472

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'VISIT2'	System	11 Nov 2020 15:20:59

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '10:17'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '11 Nov 2020 10:17'	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '97.5' F	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '74'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'bpm'	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '18'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'breaths/min'	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '108'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '62'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:43:17
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Nov 2020 17:10:23
User entered '11:57' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:10:23
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 16:35:46
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '11 Nov 2020 11:57'	System	11 Nov 2020 17:10:23
User entered empty.	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	01 Dec 2020 20:43:17
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Nov 2020 17:10:23
User entered '97.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:10:23
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 16:35:46
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:43:17
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Nov 2020 17:10:29
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:10:29
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:23
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:43:17
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Nov 2020 17:10:23
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:10:23
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 16:35:46
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'bpm'	System	11 Nov 2020 17:10:23
User entered empty.	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:43:17
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Nov 2020 17:10:23
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:10:23
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 16:35:46
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'breaths/min'	System	11 Nov 2020 17:10:23
User entered empty.	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:43:17
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Nov 2020 17:10:23
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:10:23
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 16:35:46
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	11 Nov 2020 17:10:23
User entered empty.	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:43:17
User closed query 'Per CDM re-query: Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:50:33
Query 'Per CDM re-query: Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from DM).	brittany cooksey (b) (4)	23 Nov 2020 02:09:52
User opened query 'Per CDM re-query: Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:07:54
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 10:07:40
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PER INVESTIGATOR, THIS IS CONSIDERED NORMAL FOR THIS SUBJECT. SEE CRIO FOR INVESTIGATOR EVALUATION.' (Site from System).	marsha gossett (b) (4)	16 Nov 2020 00:36:09
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		11 Nov 2020 17:10:23
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 17:10:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Nov 2020 17:10:23

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '57' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:10:23
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 16:35:46
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	11 Nov 2020 17:10:23
User entered empty.	System	11 Nov 2020 16:35:46

US3302472

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:21:17

US3302472

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:06
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 15:21:17

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:18
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:18
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'MRNA-1273 OR PLACEBO'	System	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:18
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:18
User entered '11:27'	(b) (4), (b) (6)	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '11 Nov 2020 11:27'	System	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:18
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:18
User entered 'ONCE'	System	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'INTRAMUSCULAR'	System	11 Nov 2020 16:30:51

US3302472

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:40:56

US3302472

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:31
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 15:40:56

US3302472

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:31
User entered '10:20'	(b) (4), (b) (6)	11 Nov 2020 15:40:56

US3302472

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '11 Nov 2020 10:20'	System	11 Nov 2020 15:40:56

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:41
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:41
User entered '10:19'	(b) (4), (b) (6)	11 Nov 2020 15:41:10

**US3302472**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '11 Nov 2020 10:19'	System	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:41
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered empty.	System	11 Nov 2020 15:41:10

US3302472

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:45:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:10:39

US3302472

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	11 Nov 2020 17:10:39

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:47:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a9faba19-4321-47f0-8647-43621ade996c'	System	11 Nov 2020 16:48:57
User entered 'Yes (Y)'	System	11 Nov 2020 16:48:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:48:09', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a9faba19-4321-47f0-8647-43621ade996c'	System	11 Nov 2020 16:48:57
User entered '97.5'	System	11 Nov 2020 16:48:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:48:49', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a9faba19-4321-47f0-8647-43621ade996c'	System	11 Nov 2020 16:48:57
User entered 'No (N)'	System	11 Nov 2020 16:48:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:48:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'a9faba19-4321-47f0-8647-43621ade996c'	System	11 Nov 2020 16:48:57
User entered '11 Nov 2020 11:48'	System	11 Nov 2020 16:48:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 11:47'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 14:17'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 15:12'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 2'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:56:29', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '36bb018d-1c6c-4744-ad61-27d45ca506ca'	System	12 Nov 2020 18:56:55
User entered 'Yes (Y)'	System	12 Nov 2020 18:56:55

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:56:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '36bb018d-1c6c-4744-ad61-27d45ca506ca' User entered '98.4'	System	12 Nov 2020 18:56:55
	System	12 Nov 2020 18:56:55

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:56:46', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '36bb018d-1c6c-4744-ad61-27d45ca506ca'	System	12 Nov 2020 18:56:55
User entered 'No (N)'	System	12 Nov 2020 18:56:55

**US3302472**

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

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:56:50', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '36bb018d-1c6c-4744-ad61-27d45ca506ca'	System	12 Nov 2020 18:56:55
User entered '12 Nov 2020 13:56'	System	12 Nov 2020 18:56:55

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 3'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:27:27', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c62b6f5b-b506-4396-a0ef-8386c5b506fa'	System	13 Nov 2020 18:27:52
User entered 'Yes (Y)'	System	13 Nov 2020 18:27:52

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:27:35', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c62b6f5b-b506-4396-a0ef-8386c5b506fa'	System	13 Nov 2020 18:27:52
User entered '98.5'	System	13 Nov 2020 18:27:52

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:27:42', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c62b6f5b-b506-4396-a0ef-8386c5b506fa'	System	13 Nov 2020 18:27:52
User entered 'No (N)'	System	13 Nov 2020 18:27:52

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:27:47', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c62b6f5b-b506-4396-a0ef-8386c5b506fa'	System	13 Nov 2020 18:27:52
User entered '13 Nov 2020 13:27'	System	13 Nov 2020 18:27:52

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 4'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:03:31', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9e3a3527-c40c-4124-9c09-b64361a41a30'	System	14 Nov 2020 17:03:57
User entered 'Yes (Y)'	System	14 Nov 2020 17:03:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:03:47', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9e3a3527-c40c-4124-9c09-b64361a41a30' User entered '97.4'	System	14 Nov 2020 17:03:57
	System	14 Nov 2020 17:03:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:03:52', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9e3a3527-c40c-4124-9c09-b64361a41a30'	System	14 Nov 2020 17:03:57
User entered 'No (N)'	System	14 Nov 2020 17:03:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:03:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '9e3a3527-c40c-4124-9c09-b64361a41a30'	System	14 Nov 2020 17:03:57
User entered '14 Nov 2020 12:03'	System	14 Nov 2020 17:03:57

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 5'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3fe55834-d96f-4446-b930-358db6e478ff'	System	15 Nov 2020 18:13:19
User entered 'Yes (Y)'	System	15 Nov 2020 18:13:19

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:10', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3fe55834-d96f-4446-b930-358db6e478ff'	System	15 Nov 2020 18:13:19
User entered '97.5'	System	15 Nov 2020 18:13:19

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3fe55834-d96f-4446-b930-358db6e478ff'	System	15 Nov 2020 18:13:19
User entered 'No (N)'	System	15 Nov 2020 18:13:19

**US3302472**

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

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

**Generated On: 09 Jun 2021 16:57:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:19', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3fe55834-d96f-4446-b930-358db6e478ff'	System	15 Nov 2020 18:13:19
User entered '15 Nov 2020 13:13'	System	15 Nov 2020 18:13:19

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 6'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:14', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e2e74f5b-8cd3-40af-ade4-65f2cbe6637a'	System	16 Nov 2020 19:49:32
User entered 'Yes (Y)'	System	16 Nov 2020 19:49:32

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:22', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e2e74f5b-8cd3-40af-ade4-65f2cbe6637a' User entered '97.3'	System	16 Nov 2020 19:49:32
	System	16 Nov 2020 19:49:32

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:28', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e2e74f5b-8cd3-40af-ade4-65f2cbe6637a'	System	16 Nov 2020 19:49:32
User entered 'No (N)'	System	16 Nov 2020 19:49:32

**US3302472**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:32', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e2e74f5b-8cd3-40af-ade4-65f2cbe6637a'	System	16 Nov 2020 19:49:32
User entered '16 Nov 2020 14:49'	System	16 Nov 2020 19:49:32

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 7'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:26:45', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c751a017-ba03-4d78-8125-006253b7cf34'	System	17 Nov 2020 17:26:59
User entered 'Yes (Y)'	System	17 Nov 2020 17:26:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:26:52', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c751a017-ba03-4d78-8125-006253b7cf34'	System	17 Nov 2020 17:26:59
User entered '98.5'	System	17 Nov 2020 17:26:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:26:57', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c751a017-ba03-4d78-8125-006253b7cf34'	System	17 Nov 2020 17:26:59
User entered 'No (N)'	System	17 Nov 2020 17:26:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:27:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c751a017-ba03-4d78-8125-006253b7cf34'	System	17 Nov 2020 17:26:59
User entered '17 Nov 2020 12:27'	System	17 Nov 2020 17:26:59

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:07', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e13fd585-21f8-4175-a2ea-43ea723e65a2'	System	11 Nov 2020 16:49:33
User entered 'None (1)'	System	11 Nov 2020 16:49:33

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:13', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e13fd585-21f8-4175-a2ea-43ea723e65a2'	System	11 Nov 2020 16:49:33
User entered 'No (N)'	System	11 Nov 2020 16:49:33

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:19', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e13fd585-21f8-4175-a2ea-43ea723e65a2'	System	11 Nov 2020 16:49:33
User entered 'No (N)'	System	11 Nov 2020 16:49:33

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:24', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e13fd585-21f8-4175-a2ea-43ea723e65a2'	System	11 Nov 2020 16:49:33
User entered 'None (1)'	System	11 Nov 2020 16:49:33

**US3302472**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:36', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e13fd585-21f8-4175-a2ea-43ea723e65a2'	System	11 Nov 2020 16:49:33
User entered '11 Nov 2020 11:49'	System	11 Nov 2020 16:49:33

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 11:47'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 14:17'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 15:12'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 2'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:56:59', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '941acc77-f17c-4f79-8f88-71efb7ac97ed'	System	12 Nov 2020 18:57:25
User entered 'None (1)'	System	12 Nov 2020 18:57:25

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:04', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '941acc77-f17c-4f79-8f88-71efb7ac97ed'	System	12 Nov 2020 18:57:25
User entered 'No (N)'	System	12 Nov 2020 18:57:25

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '941acc77-f17c-4f79-8f88-71efb7ac97ed'	System	12 Nov 2020 18:57:25
User entered 'No (N)'	System	12 Nov 2020 18:57:25

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:15', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '941acc77-f17c-4f79-8f88-71efb7ac97ed'	System	12 Nov 2020 18:57:25
User entered 'None (1)'	System	12 Nov 2020 18:57:25

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:22', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '941acc77-f17c-4f79-8f88-71efb7ac97ed' User entered '12 Nov 2020 13:57'	System	12 Nov 2020 18:57:25
	System	12 Nov 2020 18:57:25

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 3'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:27:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5534dd3c-8c8c-4350-aecc-d366ad440af1'	System	13 Nov 2020 18:28:24
User entered 'None (1)'	System	13 Nov 2020 18:28:24

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5534dd3c-8c8c-4350-aecc-d366ad440af1'	System	13 Nov 2020 18:28:24
User entered 'No (N)'	System	13 Nov 2020 18:28:24

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:06', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5534dd3c-8c8c-4350-aecc-d366ad440af1'	System	13 Nov 2020 18:28:24
User entered 'No (N)'	System	13 Nov 2020 18:28:24

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:12', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5534dd3c-8c8c-4350-aecc-d366ad440af1'	System	13 Nov 2020 18:28:24
User entered 'None (1)'	System	13 Nov 2020 18:28:24

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5534dd3c-8c8c-4350-aecc-d366ad440af1'	System	13 Nov 2020 18:28:24
User entered '13 Nov 2020 13:28'	System	13 Nov 2020 18:28:24

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 4'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:07', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd1c4f244-27aa-4e02-ab1d-c36fb2df9c31'	System	14 Nov 2020 17:04:31
User entered 'None (1)'	System	14 Nov 2020 17:04:31

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:13', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd1c4f244-27aa-4e02-ab1d-c36fb2df9c31'	System	14 Nov 2020 17:04:31
User entered 'No (N)'	System	14 Nov 2020 17:04:31

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:19', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd1c4f244-27aa-4e02-ab1d-c36fb2df9c31'	System	14 Nov 2020 17:04:31
User entered 'No (N)'	System	14 Nov 2020 17:04:31

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:24', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd1c4f244-27aa-4e02-ab1d-c36fb2df9c31'	System	14 Nov 2020 17:04:31
User entered 'None (1)'	System	14 Nov 2020 17:04:31

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:29', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd1c4f244-27aa-4e02-ab1d-c36fb2df9c31'	System	14 Nov 2020 17:04:31
User entered '14 Nov 2020 12:04'	System	14 Nov 2020 17:04:31

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 5'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:28', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ab9f2db-c78f-42d4-9bf3-49e2bb4de7c9'	System	15 Nov 2020 18:13:52
User entered 'None (1)'	System	15 Nov 2020 18:13:52

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:34', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ab9f2db-c78f-42d4-9bf3-49e2bb4de7c9'	System	15 Nov 2020 18:13:52
User entered 'No (N)'	System	15 Nov 2020 18:13:52

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ab9f2db-c78f-42d4-9bf3-49e2bb4de7c9'	System	15 Nov 2020 18:13:52
User entered 'No (N)'	System	15 Nov 2020 18:13:52

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:44', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ab9f2db-c78f-42d4-9bf3-49e2bb4de7c9'	System	15 Nov 2020 18:13:52
User entered 'None (1)'	System	15 Nov 2020 18:13:52

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:50', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ab9f2db-c78f-42d4-9bf3-49e2bb4de7c9'	System	15 Nov 2020 18:13:52
User entered '15 Nov 2020 13:13'	System	15 Nov 2020 18:13:52

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 6'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:40', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ed8fb265-f562-41f4-b4a6-f32e24ca1920'	System	16 Nov 2020 19:49:59
User entered 'None (1)'	System	16 Nov 2020 19:49:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:47', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ed8fb265-f562-41f4-b4a6-f32e24ca1920'	System	16 Nov 2020 19:49:59
User entered 'No (N)'	System	16 Nov 2020 19:49:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:50', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ed8fb265-f562-41f4-b4a6-f32e24ca1920'	System	16 Nov 2020 19:49:59
User entered 'No (N)'	System	16 Nov 2020 19:49:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ed8fb265-f562-41f4-b4a6-f32e24ca1920'	System	16 Nov 2020 19:49:59
User entered 'None (1)'	System	16 Nov 2020 19:49:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:49:58', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ed8fb265-f562-41f4-b4a6-f32e24ca1920'	System	16 Nov 2020 19:49:59
User entered '16 Nov 2020 14:49'	System	16 Nov 2020 19:49:59

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 7'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:27:34', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5c7fd0d7-0cb3-48b1-82f4-380229b556cd'	System	17 Nov 2020 17:27:56
User entered 'None (1)'	System	17 Nov 2020 17:27:56

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:27:40', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5c7fd0d7-0cb3-48b1-82f4-380229b556cd'	System	17 Nov 2020 17:27:56
User entered 'No (N)'	System	17 Nov 2020 17:27:56

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:27:49', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5c7fd0d7-0cb3-48b1-82f4-380229b556cd'	System	17 Nov 2020 17:27:56
User entered 'No (N)'	System	17 Nov 2020 17:27:56

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:27:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5c7fd0d7-0cb3-48b1-82f4-380229b556cd'	System	17 Nov 2020 17:27:56
User entered 'None (1)'	System	17 Nov 2020 17:27:56

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:27:59', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '5c7fd0d7-0cb3-48b1-82f4-380229b556cd'	System	17 Nov 2020 17:27:56
User entered '17 Nov 2020 12:27'	System	17 Nov 2020 17:27:56

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:46', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered 'None (0)'	System	11 Nov 2020 16:50:35

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:50', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered 'None (0)'	System	11 Nov 2020 16:50:35

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:49:56', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered 'None (0)'	System	11 Nov 2020 16:50:35

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:50:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered 'None (0)'	System	11 Nov 2020 16:50:35

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:50:05', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered 'None (0)'	System	11 Nov 2020 16:50:35

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:50:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered 'None (0)'	System	11 Nov 2020 16:50:35

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:50:25', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered 'No (N)'	System	11 Nov 2020 16:50:35

**US3302472**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-11T11:50:33', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e0c55ba7-e3f2-40fe-bd98-23ab970c2cba'	System	11 Nov 2020 16:50:35
User entered '11 Nov 2020 11:50'	System	11 Nov 2020 16:50:35

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 11:47'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 14:17'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '11 Nov 2020 15:12'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 2'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:35', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered 'None (0)'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:38', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered 'None (0)'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:42', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered 'None (0)'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:46', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered 'None (0)'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:50', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered 'None (0)'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:57:52', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered 'None (0)'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:58:07', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered 'No (N)'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-12T13:58:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'c74d37d1-69f7-4332-b4a4-da41cfd7bc1c'	System	12 Nov 2020 18:58:19
User entered '12 Nov 2020 13:58'	System	12 Nov 2020 18:58:19

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 3'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:25', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered 'None (0)'	System	13 Nov 2020 18:29:03

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:29', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered 'None (0)'	System	13 Nov 2020 18:29:03

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:33', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered 'None (0)'	System	13 Nov 2020 18:29:03

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:37', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered 'None (0)'	System	13 Nov 2020 18:29:03

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:41', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered 'None (0)'	System	13 Nov 2020 18:29:03

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:45', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered 'None (0)'	System	13 Nov 2020 18:29:03

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:51', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered 'No (N)'	System	13 Nov 2020 18:29:03

**US3302472**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-13T13:28:56', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7cc3aff4-17cc-4085-848c-f6667fb6080f'	System	13 Nov 2020 18:29:03
User entered '13 Nov 2020 13:28'	System	13 Nov 2020 18:29:03

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 4'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:36', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered 'None (0)'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:51', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered 'None (0)'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:04:55', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered 'None (0)'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered 'None (0)'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:05:03', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered 'None (0)'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:05:07', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered 'None (0)'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:05:13', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered 'No (N)'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-14T12:05:20', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '189021f7-9c46-4285-9a7b-03d25116cd29'	System	14 Nov 2020 17:05:25
User entered '14 Nov 2020 12:05'	System	14 Nov 2020 17:05:25

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 5'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:13:58', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed'	System	15 Nov 2020 18:14:31
User entered 'None (0)'	System	15 Nov 2020 18:14:31

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:14:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed'	System	15 Nov 2020 18:14:31
User entered 'None (0)'	System	15 Nov 2020 18:14:31

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:14:06', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed'	System	15 Nov 2020 18:14:31
User entered 'None (0)'	System	15 Nov 2020 18:14:31

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:14:10', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed' User entered 'None (0)'	System	15 Nov 2020 18:14:31
	System	15 Nov 2020 18:14:31

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:14:14', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed'	System	15 Nov 2020 18:14:31
User entered 'None (0)'	System	15 Nov 2020 18:14:31

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:14:17', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed'	System	15 Nov 2020 18:14:31
User entered 'None (0)'	System	15 Nov 2020 18:14:31

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:14:22', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed'	System	15 Nov 2020 18:14:31
User entered 'No (N)'	System	15 Nov 2020 18:14:31

**US3302472**

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

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

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-15T13:14:26', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09120634-d2ab-454b-abd9-d88b801803ed'	System	15 Nov 2020 18:14:31
User entered '15 Nov 2020 13:14'	System	15 Nov 2020 18:14:31

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 6'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:04', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered 'None (0)'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered 'None (0)'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:12', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered 'None (0)'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered 'None (0)'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:20', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered 'None (0)'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:23', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered 'None (0)'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:29', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered 'No (N)'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-16T14:50:36', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2e4e8268-6453-4edf-a27b-99f194159ff7'	System	16 Nov 2020 19:50:37
User entered '16 Nov 2020 14:50'	System	16 Nov 2020 19:50:37

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
Data entry locked.	System	11 Nov 2020 16:30:51
User entered 'Day 7'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:06', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered 'None (0)'	System	17 Nov 2020 17:28:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:10', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered 'None (0)'	System	17 Nov 2020 17:28:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:15', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered 'None (0)'	System	17 Nov 2020 17:28:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:35', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered 'None (0)'	System	17 Nov 2020 17:28:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:38', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered 'None (0)'	System	17 Nov 2020 17:28:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:41', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered 'None (0)'	System	17 Nov 2020 17:28:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:46', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered 'No (N)'	System	17 Nov 2020 17:28:48

**US3302472**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:57:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-11-17T12:28:51', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '10cd8263-2590-4d51-8bd9-0b1d1c95d39d'	System	17 Nov 2020 17:28:48
User entered '17 Nov 2020 12:28'	System	17 Nov 2020 17:28:48

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 16:30:51

US3302472

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:00:48
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 16:30:51

US3302472

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 15:10:04

US3302472

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:09
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 15:10:04

US3302472

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 15:10:04

US3302472

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:09
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 15:10:04

US3302472

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 15:10:12

US3302472

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	19 Nov 2020 15:10:12

US3302472

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:33
User entered 'Yes (Y)'	brittany cooksey (b) (4)	25 Nov 2020 17:04:53

US3302472

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:33
User entered '25 Nov 2020'	brittany cooksey (b) (4)	25 Nov 2020 17:04:53

US3302472

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:33
User entered 'Contact Made (CONTACT MADE)'	brittany cooksey (b) (4)	25 Nov 2020 17:04:53

US3302472

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:33
User entered empty.	brittany cooksey (b) (4)	25 Nov 2020 17:04:53

US3302472

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:42:37
User entered 'Yes (Y)'	brittany cooksey (b) (4)	25 Nov 2020 17:03:38

**US3302472**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	25 Nov 2020 17:03:38

US3302472

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:43:30
User entered 'Yes (Y)'	brittany cooksey (b) (4)	25 Nov 2020 17:03:47

US3302472

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:43:30
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).	System	08 Dec 2020 20:45:47
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 by data change (Site from System).	System	08 Dec 2020 20:45:47
User entered '02 Dec 2020' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 20:45:47
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	25 Nov 2020 17:03:47
User entered '25 Nov 2020'	brittany cooksey (b) (4) (b) (4)	25 Nov 2020 17:03:47

US3302472

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:43:30
User entered 'Contact Made (CONTACT MADE)'	brittany cooksey (b) (4)	25 Nov 2020 17:03:47

US3302472

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:43:30
User entered empty.	brittany cooksey (b) (4)	25 Nov 2020 17:03:47

US3302472

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:43:36
User entered 'Yes (Y)'	brittany cooksey (b) (4)	25 Nov 2020 17:03:52

**US3302472**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	25 Nov 2020 17:03:52

US3302472

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:43:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 18:11:16

US3302472

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:43:53
User entered '09 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 18:11:16

US3302472

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[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 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:43:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Dec 2020 18:11:16

**US3302472**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'VISIT3'	System	09 Dec 2020 18:11:16

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered '09 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered '09:55'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '09 Dec 2020 09:55'	System	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered '97.8' F	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered '69'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'bpm'	System	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered '16'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'breaths/min'	System	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User entered '93'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:14
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 11:09:16
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as is NCS per PI' (Site from System).	Wendy Taylor (b) (4)	21 Dec 2020 22:55:21
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		09 Dec 2020 18:11:47
User entered '59'	(b) (4), (b) (6)	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'mmHg'	System	09 Dec 2020 18:11:47

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29

US3302472

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29

US3302472

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 18:11:58

US3302472

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:45:57
User entered '09 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 18:11:58

US3302472

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 18:12:10

US3302472

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:13
User entered '09 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 18:12:10

US3302472

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:13
User entered '09:58'	(b) (4), (b) (6)	09 Dec 2020 18:12:10

US3302472

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered '09 Dec 2020 09:58'	System	09 Dec 2020 18:12:10

US3302472

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 18:12:13

US3302472

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'I'	System	09 Dec 2020 18:12:13

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-11T11:42:56', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09e3fbca-d04b-4ac5-b16f-640d436db2ef'	System	11 Dec 2020 16:43:10
User entered 'No (N)'	System	11 Dec 2020 16:43:10

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (f178058b7b9f7956)', Time: '2020-12-11T11:43:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09e3fbca-d04b-4ac5-b16f-640d436db2ef'	System	11 Dec 2020 16:43:10
User entered 'No (N)'	System	11 Dec 2020 16:43:10

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-11T11:43:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '09e3fbca-d04b-4ac5-b16f-640d436db2ef'	System	11 Dec 2020 16:43:10
User entered '11 Dec 2020 11:43:08'	System	11 Dec 2020 16:43:10

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-16T06:56:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '8927578e-dd40-41eb-b6de-6f6ef08f4fe8'	System	16 Dec 2020 11:56:18
User entered 'No (N)'	System	16 Dec 2020 11:56:18

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (f178058b7b9f7956)', Time: '2020-12-16T06:55:48', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '8927578e-dd40-41eb-b6de-6f6ef08f4fe8'	System	16 Dec 2020 11:56:18
User entered 'No (N)'	System	16 Dec 2020 11:56:18

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-16T06:56:12', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '8927578e-dd40-41eb-b6de-6f6ef08f4fe8' User entered '16 Dec 2020 06:56:12'	System	16 Dec 2020 11:56:18
	System	16 Dec 2020 11:56:18

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-23T09:46:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered 'Yes (Y)'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (f178058b7b9f7956)', Time: '2020-12-23T09:46:51', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered 'No (N)'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-23T09:49:49', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered 'Yes (Y)'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '1'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '1'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '1'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '1'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '1'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '1'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:51:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '0'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (f178058b7b9f7956)', Time: '2020-12-23T09:52:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-23T09:53:21', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered 'Yes (Y)'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (f178058b7b9f7956)', Time: '2020-12-23T09:53:31', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-23T09:53:36', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '27241f88-dd41-43d4-8047-eb1ebf69b39a'	System	23 Dec 2020 14:53:48
User entered '23 Dec 2020 09:53:36'	System	23 Dec 2020 14:53:48

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-30T09:28:03', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '53ba82ec-2b2c-41c9-b08f-77f70d734a90'	System	30 Dec 2020 14:29:34
User entered 'Yes (Y)'	System	30 Dec 2020 14:29:34

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with 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 (f178058b7b9f7956)', Time: '2020-12-30T09:28:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '53ba82ec-2b2c-41c9-b08f-77f70d734a90'	System	30 Dec 2020 14:29:34
User entered 'Yes (Y)'	System	30 Dec 2020 14:29:34

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please 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 (f178058b7b9f7956)', Time: '2020-12-30T09:28:32', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '53ba82ec-2b2c-41c9-b08f-77f70d734a90'	System	30 Dec 2020 14:29:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 14:29:34

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-30T09:28:44', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '53ba82ec-2b2c-41c9-b08f-77f70d734a90'	System	30 Dec 2020 14:29:34
User entered 'No (N)'	System	30 Dec 2020 14:29:34

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2020-12-30T09:29:08', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '53ba82ec-2b2c-41c9-b08f-77f70d734a90'	System	30 Dec 2020 14:29:34
User entered 'Yes (Y)'	System	30 Dec 2020 14:29:34

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (f178058b7b9f7956)', Time: '2020-12-30T09:29:25', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '53ba82ec-2b2c-41c9-b08f-77f70d734a90'	System	30 Dec 2020 14:29:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 14:29:34

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2020-12-30T09:29:29', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '53ba82ec-2b2c-41c9-b08f-77f70d734a90'	System	30 Dec 2020 14:29:34
User entered '30 Dec 2020 09:29:29'	System	30 Dec 2020 14:29:34

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2021-01-06T11:11:31', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered 'Yes (Y)'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (f178058b7b9f7956)', Time: '2021-01-06T11:09:53', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered 'Yes (Y)'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Please 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 (f178058b7b9f7956)', Time: '2021-01-06T11:10:03', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (f178058b7b9f7956)', Time: '2021-01-06T11:10:09', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered 'Yes (Y)'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '0'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:10:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '1'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (f178058b7b9f7956)', Time: '2021-01-06T11:11:05', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 16:11:40

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (f178058b7b9f7956)', Time: '2021-01-06T11:11:15', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered 'Yes (Y)'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (f178058b7b9f7956)', Time: '2021-01-06T11:11:21', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f178058b7b9f7956)', Time: '2021-01-06T11:11:35', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '91d3f29e-1542-4cd6-b143-b303308cb080'	System	06 Jan 2021 16:11:40
User entered '06 Jan 2021 11:11:35'	System	06 Jan 2021 16:11:40

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:46:51', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered 'Yes (Y)'	System	13 Jan 2021 16:48:12
	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:46:58', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered 'Yes (Y)'	System	13 Jan 2021 16:48:12
	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:07', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8'	System	13 Jan 2021 16:48:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:16', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered 'Yes (Y)'	System	13 Jan 2021 16:48:12
	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '0'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '0'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '0'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '0'	System	13 Jan 2021 16:48:12
	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '0'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:39', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered '1'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:44', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8'	System	13 Jan 2021 16:48:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 16:48:12

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:49', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8' User entered 'Yes (Y)'	System	13 Jan 2021 16:48:12
	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Please 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:52', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8'	System	13 Jan 2021 16:48:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-13T11:47:58', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '769603da-ddc1-4738-b9b2-c400e4b727f8'	System	13 Jan 2021 16:48:12
User entered '13 Jan 2021 11:47:58'	System	13 Jan 2021 16:48:12

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-22T12:02:40', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ba8ca7b-31b0-4291-bf33-cbbfbf4e79f3'	System	22 Jan 2021 17:04:46
User entered 'No (N)'	System	22 Jan 2021 17:04:46

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-22T12:01:54', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ba8ca7b-31b0-4291-bf33-cbbfbf4e79f3'	System	22 Jan 2021 17:04:46
User entered 'No (N)'	System	22 Jan 2021 17:04:46

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-22T12:03:06', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '1ba8ca7b-31b0-4291-bf33-cbbfbf4e79f3' User entered '22 Jan 2021 12:03:06'	System	22 Jan 2021 17:04:46
	System	22 Jan 2021 17:04:46

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-27T04:17:22', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7218de82-2437-4dc1-9115-f5f2a4876a4b' User entered 'No (N)'	System	27 Jan 2021 09:17:56
	System	27 Jan 2021 09:17:56

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-27T04:17:46', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7218de82-2437-4dc1-9115-f5f2a4876a4b' User entered 'No (N)'	System	27 Jan 2021 09:17:56

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-01-27T04:17:53', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '7218de82-2437-4dc1-9115-f5f2a4876a4b' User entered '27 Jan 2021 04:17:53'	System	27 Jan 2021 09:17:56
	System	27 Jan 2021 09:17:56

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-03T02:54:49', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e48cfd78-766a-4eff-a4b4-84dfa7b3eb4a' User entered 'No (N)'	System	03 Feb 2021 07:55:15
	System	03 Feb 2021 07:55:15

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-03T02:54:59', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e48cfd78-766a-4eff-a4b4-84dfa7b3eb4a' User entered 'No (N)'	System	03 Feb 2021 07:55:15

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-03T02:55:11', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'e48cfd78-766a-4eff-a4b4-84dfa7b3eb4a' User entered '03 Feb 2021 02:55:11'	System	03 Feb 2021 07:55:15
	System	03 Feb 2021 07:55:15

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-10T00:01:48', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd3fc716a-528b-4600-8caf-39db746b4163'	System	10 Feb 2021 05:03:37
User entered 'No (N)'	System	10 Feb 2021 05:03:37

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-10T00:02:01', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd3fc716a-528b-4600-8caf-39db746b4163'	System	10 Feb 2021 05:03:37
User entered 'No (N)'	System	10 Feb 2021 05:03:37

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-10T00:02:24', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'd3fc716a-528b-4600-8caf-39db746b4163'	System	10 Feb 2021 05:03:37
User entered '10 Feb 2021 00:02:24'	System	10 Feb 2021 05:03:37

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-17T04:57:26', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b2262d0e-6923-4766-8d48-974d7842c2a9'	System	17 Feb 2021 09:57:53
User entered 'No (N)'	System	17 Feb 2021 09:57:53

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-17T04:57:35', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b2262d0e-6923-4766-8d48-974d7842c2a9'	System	17 Feb 2021 09:57:53
User entered 'No (N)'	System	17 Feb 2021 09:57:53

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-17T04:57:49', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'b2262d0e-6923-4766-8d48-974d7842c2a9'	System	17 Feb 2021 09:57:53
User entered '17 Feb 2021 04:57:49'	System	17 Feb 2021 09:57:53

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:19:00

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-24T07:38:16-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '077e4f63-da86-4707-93e2-fb989d38b8d8' User entered 'No (N)'	System	24 Feb 2021 12:38:30
	System	24 Feb 2021 12:38:30

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-24T07:38:23-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '077e4f63-da86-4707-93e2-fb989d38b8d8' User entered 'No (N)'	System	24 Feb 2021 12:38:30
	System	24 Feb 2021 12:38:30

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-24T07:38:27-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '077e4f63-da86-4707-93e2-fb989d38b8d8' User entered '24 Feb 2021 12:38:27'	System	24 Feb 2021 12:38:30
	System	24 Feb 2021 12:38:30

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-03T04:19:37-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '88f30cb1-d8ac-41d9-90ee-cdf94e9f2e66'	System	03 Mar 2021 09:19:57
User entered 'No (N)'	System	03 Mar 2021 09:19:57

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-03T04:19:48-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '88f30cb1-d8ac-41d9-90ee-cdf94e9f2e66'	System	03 Mar 2021 09:19:57
User entered 'No (N)'	System	03 Mar 2021 09:19:57

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-03T04:19:55-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '88f30cb1-d8ac-41d9-90ee-cdf94e9f2e66'	System	03 Mar 2021 09:19:57
User entered '03 Mar 2021 04:19:55'	System	03 Mar 2021 09:19:57

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-10T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ccfcbc7d-0bef-43d8-8261-daeb1b8bb6f2'	System	10 Mar 2021 05:04:24
User entered 'No (N)'	System	10 Mar 2021 05:04:24

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-10T00:02:40-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ccfcbc7d-0bef-43d8-8261-daeb1b8bb6f2'	System	10 Mar 2021 05:04:24
User entered 'No (N)'	System	10 Mar 2021 05:04:24

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-10T00:02:46-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: 'ccfc7d-0bef-43d8-8261-daeb1b8bb6f2'	System	10 Mar 2021 05:04:24
User entered '10 Mar 2021 00:02:46'	System	10 Mar 2021 05:04:24

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-17T00:05:26-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '88b64bac-0bc5-4d4c-8d8d-df3ce3b5f1c1' User entered 'No (N)'	System	17 Mar 2021 04:05:45
	System	17 Mar 2021 04:05:45

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-17T00:05:35-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '88b64bac-0bc5-4d4c-8d8d-df3ce3b5f1c1'	System	17 Mar 2021 04:05:45
User entered 'No (N)'	System	17 Mar 2021 04:05:45

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-17T00:05:41-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '88b64bac-0bc5-4d4c-8d8d-df3ce3b5f1c1' User entered '17 Mar 2021 00:05:41'	System	17 Mar 2021 04:05:45
	System	17 Mar 2021 04:05:45

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-24T06:12:23-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3d35804f-8cb8-4fc4-9dfe-2f05388b7645'	System	24 Mar 2021 10:12:42
User entered 'No (N)'	System	24 Mar 2021 10:12:42

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-24T06:12:31-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3d35804f-8cb8-4fc4-9dfe-2f05388b7645'	System	24 Mar 2021 10:12:42
User entered 'No (N)'	System	24 Mar 2021 10:12:42

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-24T06:12:39-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '3d35804f-8cb8-4fc4-9dfe-2f05388b7645'	System	24 Mar 2021 10:12:42
User entered '24 Mar 2021 06:12:39'	System	24 Mar 2021 10:12:42

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-31T00:02:56-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '4bf98cd9-1e2f-4936-a765-0c0639e8b001'	System	31 Mar 2021 04:04:22
User entered 'No (N)'	System	31 Mar 2021 04:04:22

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-31T00:03:05-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '4bf98cd9-1e2f-4936-a765-0c0639e8b001'	System	31 Mar 2021 04:04:22
User entered 'No (N)'	System	31 Mar 2021 04:04:22

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-03-31T00:03:12-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '4bf98cd9-1e2f-4936-a765-0c0639e8b001' User entered '31 Mar 2021 00:03:12'	System	31 Mar 2021 04:04:22
	System	31 Mar 2021 04:04:22

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-07T00:02:30-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '23f77ddc-3987-4b45-bbf9-5b96f22f43f6'	System	07 Apr 2021 04:04:01
User entered 'No (N)'	System	07 Apr 2021 04:04:01

US3302472

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-07T00:02:44-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '23f77ddc-3987-4b45-bbf9-5b96f22f43f6'	System	07 Apr 2021 04:04:01
User entered 'No (N)'	System	07 Apr 2021 04:04:01

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-07T00:02:48-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '23f77ddc-3987-4b45-bbf9-5b96f22f43f6'	System	07 Apr 2021 04:04:01
User entered '07 Apr 2021 00:02:48'	System	07 Apr 2021 04:04:01

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-14T05:15:42-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '17f08f55-dd8b-4e9d-99d2-d55b775cc505'	System	14 Apr 2021 13:32:50
User entered 'No (N)'	System	14 Apr 2021 13:32:50

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-14T05:15:50-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '17f08f55-dd8b-4e9d-99d2-d55b775cc505'	System	14 Apr 2021 13:32:50
User entered 'No (N)'	System	14 Apr 2021 13:32:50

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-14T05:15:59-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '17f08f55-dd8b-4e9d-99d2-d55b775cc505'	System	14 Apr 2021 13:32:50
User entered '14 Apr 2021 05:15:59'	System	14 Apr 2021 13:32:50

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-21T04:33:05-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2bc203f0-eca9-436f-95f8-7b19bae89bda' User entered 'No (N)'	System	21 Apr 2021 08:33:22
	System	21 Apr 2021 08:33:22

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-21T04:33:11-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2bc203f0-eca9-436f-95f8-7b19bae89bda' User entered 'No (N)'	System	21 Apr 2021 08:33:22
	System	21 Apr 2021 08:33:22

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-21T04:33:18-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '2bc203f0-eca9-436f-95f8-7b19bae89bda' User entered '21 Apr 2021 04:33:18'	System	21 Apr 2021 08:33:22
	System	21 Apr 2021 08:33:22

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-28T03:53:24-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '554d8666-e263-4018-b66e-b865009b486b'	System	29 Apr 2021 00:47:07
User entered 'No (N)'	System	29 Apr 2021 00:47:07

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

Have you been exposed to someone with 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 (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-28T03:53:29-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '554d8666-e263-4018-b66e-b865009b486b' User entered 'No (N)'	System	29 Apr 2021 00:47:07

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-04-28T03:53:34-04:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '554d8666-e263-4018-b66e-b865009b486b' User entered '28 Apr 2021 03:53:34'	System	29 Apr 2021 00:47:07

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '07 Dec 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '11 Dec 2022 23:59'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '14 Dec 2022 00:01'	System	20 Nov 2020 12:19:00

**US3302472**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:57:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:00
Amendment Manager: User entered '18 Dec 2022 23:59'	System	20 Nov 2020 12:19:00

US3302472

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:57:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:54:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-27T11:33:23-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '603c8004-ccbb-4d11-adbe-dfa2fe766810'	System	27 Feb 2021 16:33:44
User entered 'No (N)'	System	27 Feb 2021 16:33:44

US3302472

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:57:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:54:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6F51595-3DF3-4B61-8A15-EB638AC92844)', Time: '2021-02-27T11:33:42-05:00', User OID: 'PatientReportedOutcome (US3302472)', ODM File OID: '603c8004-ccbb-4d11-adbe-dfa2fe766810' User entered '27 Feb 2021 16:33:42'	System	27 Feb 2021 16:33:44
	System	27 Feb 2021 16:33:44

US3302472

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:38:09
Data hard unlocked.	(b) (4), (b) (6)	17 Apr 2021 17:18:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:22:59
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:22:47
DataPoint Un-verified.	Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
Signature has been broken.	Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:35:39
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 15:17:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 15:17:52
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	04 Feb 2021 15:17:52
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 15:17:44
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	04 Feb 2021 15:17:44
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 21:47:08

US3302472

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:46:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 17:43:53

US3302472

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:38:09
Data hard unlocked.	(b) (4), (b) (6)	17 Apr 2021 17:18:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Un-verified.	(b) (4) Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
Signature has been broken.	Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
User entered '04 Jan 2021' reason for change: Data Entry Error	Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:35:43
User closed query 'Please review the source; the CRA is unable to locate this information to verify' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:35:29
Query 'Please review the source; the CRA is unable to locate this information to verify' answered with 'not done' (Site from CRA).	brittany cooksey (b) (4)	04 Feb 2021 15:18:09
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	04 Feb 2021 15:17:44
User opened query 'Please review the source; the CRA is unable to locate this information to verify' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 14:50:33
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 21:47:10
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:46:45
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Jan 2021 17:44:22

US3302472

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	29 Jan 2021 17:44:22
answered by data change (Site from System). User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 17:44:22
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Jan 2021 17:43:53
User entered '14 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 17:43:53

US3302472

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:38:09
Data hard unlocked.	(b) (4), (b) (6)	17 Apr 2021 17:18:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Un-verified.	(b) (4) Brittany Belcher (b) (4)	24 Mar 2021 19:22:59
Signature has been broken.	Brittany Belcher (b) (4)	24 Mar 2021 19:22:59
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	24 Mar 2021 19:22:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:35:46
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	04 Feb 2021 15:17:44
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 21:47:12
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:46:45
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	29 Jan 2021 17:43:53

US3302472

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:38:09
Data hard unlocked.	(b) (4), (b) (6)	17 Apr 2021 17:18:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Un-verified.	(b) (4) Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
Signature has been broken.	(b) (4) Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
User entered 'Site attempted to contact subject to complete their Safety Call 85. Subject didn't return phone call.' reason for change: Data Entry Error	Brittany Belcher (b) (4)	24 Mar 2021 19:22:47
User signature succeeded.	(b) (4) Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:35:49
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	04 Feb 2021 15:17:44
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 21:47:14
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:46:45
User entered 'no answer'	(b) (4), (b) (6)	29 Jan 2021 17:43:53

US3302472

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:17
Data hard unlocked.	(b) (4), (b) (6)	17 Apr 2021 17:18:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:36:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 17:43:57

US3302472

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:17
Data hard unlocked.	(b) (4), (b) (6)	17 Apr 2021 17:18:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:26:29
User entered 'l'	System	29 Jan 2021 17:43:57

US3302472

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 02:25:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4)	08 Feb 2021 21:32:14

US3302472

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 02:25:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '08 Feb 2021'	(b) (4) Wendy Taylor (b) (4)	08 Feb 2021 21:32:14

US3302472

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 02:25:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	08 Feb 2021 21:32:14

US3302472

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 02:25:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4)	08 Feb 2021 21:32:14

US3302472

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 02:25:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	08 Feb 2021 21:32:21

US3302472

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
User entered 'I'	System	08 Feb 2021 21:32:21

US3302472

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 12:59:40
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	08 Mar 2021 16:24:20

US3302472

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 12:59:40
User entered '08 Mar 2021'	Kendal Nelson (b) (4)	08 Mar 2021 16:24:20

US3302472

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 12:59:40
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4)	08 Mar 2021 16:24:20

US3302472

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 12:59:40
User entered empty.	Kendal Nelson (b) (4)	08 Mar 2021 16:24:20

US3302472

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 12:59:57
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	08 Mar 2021 16:24:26

US3302472

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:18:52
User entered 'I'	System	08 Mar 2021 16:24:26

US3302472

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	09 Apr 2021 13:11:40

US3302472

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '09 Apr 2021'	Wendy Taylor (b) (4)	09 Apr 2021 13:11:40

US3302472

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	09 Apr 2021 13:11:40

US3302472

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
User entered empty.	(b) (4)	
	Wendy Taylor (b) (4)	09 Apr 2021 13:11:40

US3302472

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	09 Apr 2021 13:11:46

**US3302472**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 13:11:46

US3302472

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 18:27:58

US3302472

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '27 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 18:27:58

US3302472

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Apr 2021 18:27:58

**US3302472**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	28 Apr 2021 18:27:58

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '27 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '08:55'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 08:55'	System	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '97.0' F	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '78'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

**US3302472**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '108'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '71'	(b) (4), (b) (6)	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Apr 2021 18:28:19

US3302472

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 18:28:25

US3302472

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 18:28:25

US3302472

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 18:28:33

US3302472

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '27 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 18:28:33

US3302472

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered '08:58'	(b) (4), (b) (6)	28 Apr 2021 18:28:33

**US3302472**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 08:58'	System	28 Apr 2021 18:28:33

US3302472

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 18:29:05

**US3302472**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 18:29:05

US3302472

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:57:13

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:04:04
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:40:47
User entered '02 Feb 2021'	Brittany Belcher (b) (4)	16 Apr 2021 18:41:39

US3302472

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:57:13

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:04:04
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:40:47
User entered '09:08'	Brittany Belcher (b) (4)	16 Apr 2021 18:41:39

US3302472

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:57:13

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:04:04
User entered '02 Feb 2021 09:08'	System	16 Apr 2021 18:41:39

US3302472

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:57:13

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:04:04
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:40:47
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Brittany Belcher (b) (4)	16 Apr 2021 18:41:39

US3302472

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:57:13

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:04:04
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:40:47
User entered 'No (N)'	Brittany Belcher (b) (4)	16 Apr 2021 18:41:39

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:05
User closed query 'Per ETRTR: Please complete COVID-19 assessments pages and Illness visit pages. Thank You!' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 12:23:49
Query 'Per ETRTR: Please complete COVID-19 assessments pages and Illness visit pages. Thank You!' answered with 'this subject did not have visits she never notified the site. This was reported at her visit and SAE was reported immediately ' (Site from CRA).	Wendy Taylor (b) (4)	04 Mar 2021 23:20:37
User opened query 'Per ETRTR: Please complete COVID-19 assessments pages and Illness visit pages. Thank You!' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 08:47:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:05:44

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:44

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:05
User closed query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because OL Visit did not occur during a Protocol Scheduled Visit. Thank You! ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 12:24:19
Query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because OL Visit did not occur during a Protocol Scheduled Visit. Thank You! ' answered with 'updated ' (Site from CRA).	Wendy Taylor (b) (4)	04 Mar 2021 23:21:06
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because OL Visit did not occur during a Protocol Scheduled Visit. Thank You! ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 14:41:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:44

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 19:05:44

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:51:04
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
User entered '0'	(b) (4) marsha gossett (b) (4)	01 Apr 2021 21:10:34
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 15:30:04

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:51:01
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) marsha gossett (b) (4)	01 Apr 2021 21:10:34
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 15:30:04

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:43:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'I'	System	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'I'	System	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered empty.	System	02 Feb 2021 19:07:02
DataPoint set to visible.	System	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered empty.	System	02 Feb 2021 19:07:02
DataPoint set to visible.	System	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '09:13'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Feb 2021 09:13'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '70'	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'bpm'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'breaths/min'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '135'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '92'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered empty.	System	02 Feb 2021 19:07:02
DataPoint set to visible.	System	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '09:46'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Feb 2021 09:46'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '65'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'bpm'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '16'	(b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'breaths/min'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '134'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:58:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '85'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Feb 2021 19:07:02

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:07:12

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:20
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:12

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:01:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:01:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:01:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mRNA-1273'	System	02 Feb 2021 19:07:38
DataPoint set to visible.	System	02 Feb 2021 19:05:57

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:01:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:01:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '09:16'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Feb 2021 09:16'	System	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:01:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:01:01
User entered 'ONCE'	System	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 19:07:38

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:05:37

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:37

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '08:55'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:37

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Feb 2021 08:55'	System	02 Feb 2021 19:05:37

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:05:29

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:29

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '08:54'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:05:29

**US3302472**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:57:13**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Feb 2021 08:54'	System	02 Feb 2021 19:05:29

US3302472

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:54
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:07:54

**US3302472**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'I'	System	02 Feb 2021 19:07:54

US3302472

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:02:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	09 Feb 2021 14:24:49

US3302472

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:02:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '09 Feb 2021'	(b) (4) Wendy Taylor (b) (4)	09 Feb 2021 14:24:49

US3302472

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:02:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	09 Feb 2021 14:24:49

US3302472

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:02:58
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered empty.	Wendy Taylor (b) (4)	09 Feb 2021 14:24:49

US3302472

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:03:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	09 Feb 2021 14:24:56

**US3302472**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
User entered 'I'	System	09 Feb 2021 14:24:56

US3302472

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
User entered '1'	System	09 Feb 2021 14:24:56
DataPoint set to visible.	System	09 Feb 2021 14:24:56

US3302472

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:04:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:23:55

US3302472

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:04:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:55

US3302472

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:04:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:23:55

**US3302472**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'OLD29'	System	02 Mar 2021 20:23:55

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '08:49'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Mar 2021 08:49'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '98.0' F	(b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '71'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'bpm'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '18'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'breaths/min'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '104'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '69'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '09:37'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

**US3302472**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Mar 2021 09:37'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '73'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'bpm'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'breaths/min'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '116'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:05:10
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '70'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mmHg'	System	02 Mar 2021 20:24:46

US3302472

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:04
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:24:54

US3302472

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:04
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:24:54

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:23
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:23
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:23
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'mRNA-1273'	System	02 Mar 2021 20:25:11
DataPoint set to visible.	System	09 Feb 2021 14:24:56

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:23
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:23
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered '09:07'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered '02 Mar 2021 09:07'	System	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:23
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:06:23
User entered 'ONCE'	System	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 20:25:11

US3302472

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:21:08
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 19:03:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:25:49

**US3302472**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:34:26
User entered 'I'	System	02 Mar 2021 20:25:49

US3302472

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:22:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	09 Mar 2021 16:06:06

**US3302472**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:57:13**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:22:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
User entered '09 Mar 2021'	(b) (4) Wendy Taylor (b) (4)	09 Mar 2021 16:06:06

US3302472

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:22:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	09 Mar 2021 16:06:06

US3302472

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:22:58
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
User entered empty.	Wendy Taylor (b) (4)	09 Mar 2021 16:06:06

US3302472

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:03:51
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:27:24
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	09 Mar 2021 16:06:14

**US3302472**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:57:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:37:09
User entered 'I'	System	09 Mar 2021 16:06:14

US3302472

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 19:43:27

US3302472

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '30 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 19:43:27

US3302472

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Mar 2021 19:43:27

**US3302472**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:57:13**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 19:43:27

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '30 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '08:32'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

**US3302472**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 08:32'	System	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '97.5' F	(b) (4), (b) (6)	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '65'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

**US3302472**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '136'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

**US3302472**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '72'	(b) (4), (b) (6)	31 Mar 2021 19:43:41

**US3302472**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:57:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 19:43:41

US3302472

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 19:43:50

US3302472

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:43:50

US3302472

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 19:43:57

US3302472

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '30 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 19:43:57

US3302472

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:09:00
	(b) (4)	
User entered '08:34'	(b) (4), (b) (6)	31 Mar 2021 19:43:57

**US3302472**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:57:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 08:34'	System	31 Mar 2021 19:43:57

US3302472

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:57:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:48
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 96, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Per Safety Follow-up Diary Day 96, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Per source, site attempted to call subject requesting the changes to report and have to leave a message. Site didn't get in touch with subject about any of the changes until later in the trial, after the subject was d/c'd from the hospital and all SAE information was reported. ' (Site from DM). User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 96, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 08:21:36
	Brittany Belcher (b) (4)	06 Apr 2021 18:31:39
	(b) (4), (b) (6)	02 Apr 2021 18:32:34
	(b) (4), (b) (6)	31 Mar 2021 21:15:30
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Un-verified.	Brittany Belcher (b) (4)	02 Feb 2021 14:39:18

US3302472

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:57:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	02 Feb 2021 14:39:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:43:20
User entered 'No (N)'	brittany cooksey (b) (4)	23 Nov 2020 02:19:56

US3302472

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:07
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:54:58
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 18:08:40
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 18:08:33
User entered	System	03 Feb 2021 14:39:08
'USA-US087-2021-mRNA-1273-P301000017'		
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 14:39:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Since the subject was in the hospital for Covid, please use the medical records to complete the Covid Assessment page. We are aware that the site did not complete the assessments.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 01:42:41
Query 'Since the subject was in the hospital for Covid, please use the medical records to complete the Covid Assessment page. We are aware that the site did not complete the assessments.' answered with 'Completed.' (Site from CRA).	Brittany Belcher (b) (4)	16 Apr 2021 18:42:42
User opened query 'Since the subject was in the hospital for Covid, please use the medical records to complete the Covid Assessment page. We are aware that the site did not complete the assessments.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:42:31
User closed query 'Please add the Covid-19 Assessment Page - since subject was in the hospital due to Covid.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:42:31
Query 'Please add the Covid-19 Assessment Page - since subject was in the hospital due to Covid.' answered with 'Site was completely unaware of the subject having Covid-19 and receiving treatment for Covid-19 until after subject was discharged from the hospital. Site didn't not complete any Covid-19 assessments as we were unaware to do so. Please advise if the assessment page is needing to be completed as the Site didn't complete Covid-19 assessments.' (Site from CRA).	Brittany Belcher (b) (4)	16 Apr 2021 11:55:02
User opened query 'Please add the Covid-19 Assessment Page - since subject was in the hospital due to Covid.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 05:26:01
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:17:13
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	02 Feb 2021 14:43:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Feb 2021 14:43:28
Data point term sent to Coder	System	02 Feb 2021 14:42:17

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Covid-19'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:16
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:19
User entered 'No (N)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if COVID-19 testing was performed during hospital admission. If so, please provide the results, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:44:22
Query 'PV Query: Please confirm if COVID-19 testing was performed during hospital admission. If so, please provide the results, including date of collection and type of testing.' answered with 'Per SAE medical records (from hospital; page 2 of D/C Summary), subject tested positive for COVID-19.' (Site from Safety).	Brittany Belcher (b) (4)	14 Apr 2021 13:05:43
User opened query 'PV Query: Please confirm if COVID-19 testing was performed during hospital admission. If so, please provide the results, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 00:22:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:01:10
User closed query 'PV Query: Please complete the symptoms log in COVID-19 Assessments tab.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:50:42
Query 'PV Query: Please complete the symptoms log in COVID-19 Assessments tab.' answered with 'updated ' (Site from Safety).	Wendy Taylor (b) (4)	15 Mar 2021 13:34:01
User opened query 'PV Query: Please complete the symptoms log in COVID-19 Assessments tab.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 18:45:51
User closed query 'PV Query: Please provided symptom logs for event of COVID-19 when available.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:34:11
Query 'PV Query: Please provided symptom logs for event of COVID-19 when available.' answered with 'updated ' (Site from Safety).	Wendy Taylor (b) (4)	04 Mar 2021 21:09:04
User opened query 'PV Query: Please provided symptom logs for event of COVID-19 when available.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:49:23
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:31
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:34
User entered empty.	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

**US3302472**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:39
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 14:42:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 14:42:59
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	02 Feb 2021 14:42:59
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 14:41:56
User entered empty.	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:41
User entered '30 Dec 2020'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:43
User entered empty.	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

**US3302472**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:45
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Feb 2021 14:42:59
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Feb 2021 14:41:56
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:17:59
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

US3302472

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:00
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:02
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	03 Feb 2021 07:25:23
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Brittany Belcher (b) (4)	02 Feb 2021 14:46:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		02 Feb 2021 14:42:59
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	02 Feb 2021 14:42:59
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Feb 2021 14:42:59
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	02 Feb 2021 14:42:59
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Feb 2021 14:41:56
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:06
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:07
User entered '30 Dec 2020'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:11
User entered empty.	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:13
User entered empty.	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:14
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:16
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

US3302472

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:18
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:20
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:21
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:23
User closed query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:02:35
Query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' answered with 'updated. ' (Site from DM).	Brittany Belcher (b) (4)	12 Feb 2021 14:45:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	12 Feb 2021 14:45:06
User opened query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:38:06
User entered 'None (NONE)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

None

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:59:43
User closed query 'Per CDM CLR re-query: Thank you for your answer. Please keep this query open until there is information about Concomitant medications/procedures. Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:10:44
Query 'Per CDM CLR re-query: Thank you for your answer. Please keep this query open until there is information about Concomitant medications/procedures. Thank you!' answered with 'Con Med and AE list updated.' (Site from DM).	Brittany Belcher (b) (4)	05 Apr 2021 20:23:04
DataPoint Un-verified.	Brittany Belcher (b) (4)	05 Apr 2021 20:22:44
User entered '0' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 20:22:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:18:39
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 21:18:35
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:18:30
User opened query 'Per CDM CLR re-query: Thank you for your answer. Please keep this query open until there is information about Concomitant medications/procedures. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 07:49:42
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 07:49:42

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Generated On: 09 Jun 2021 16:57:13

None

Audit	User	Time (GMT)
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.  ' answered with 'waiting on records ' (Site from DM).	Wendy Taylor (b) (4)	15 Mar 2021 13:34:24
Query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:01:33
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 01:11:27
User opened query 'PV Query: As the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:47:52
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Feb 2021 14:47:09
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	02 Feb 2021 14:47:09
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Feb 2021 14:41:56
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 20:59:27
DataPoint Un-verified.	Brittany Belcher (b) (4)	05 Apr 2021 20:22:44
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 20:22:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:18:37
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:18:41
User entered '0'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 20:59:10
User closed query 'Please review source and revise if needed. Source states that the outcome of AE is Recovering/Resolving.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 20:58:47
Query 'Please review source and revise if needed. Source states that the outcome of AE is Recovering/Resolving.' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	05 Apr 2021 20:23:10
User opened query 'Please review source and revise if needed. Source states that the outcome of AE is Recovering/Resolving.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 21:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 21:18:48
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:18:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 21:19:37
User entered empty.	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'IQVIA Medical query: Please consider whether acute respiratory failure with hypoxia as noted in hospital records meets criteria for SAE/AE reporting and update the report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:44:27
Query 'IQVIA Medical query: Please consider whether acute respiratory failure with hypoxia as noted in hospital records meets criteria for SAE/AE reporting and update the report if appropriate.' answered with 'Per PI, this is secondary to COVID-19 and does not feel that this should be a SAE. ' (Site from Safety).	Brittany Belcher (b) (4)	14 Apr 2021 13:20:42
User opened query 'IQVIA Medical query: Please consider whether acute respiratory failure with hypoxia as noted in hospital records meets criteria for SAE/AE reporting and update the report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 00:26:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query ' PV Query: Initial Query response was entered as "updated", yet symptom log in COVID-19 assessments tab, has not been updated. Please complete the symptoms log in COVID-19 Assessments tab.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:55:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:00:23
Query ' PV Query: Initial Query response was entered as "updated", yet symptom log in COVID-19 assessments tab, has not been updated. Please complete the symptoms log in COVID-19 Assessments tab.' answered with 'Subject didn't complete any Convalescent visits as she was treated at the hospital for Covid-19. Site was unaware of her Covid-19 diagnosis until after subject was discharged and fully recovered. ' (Site from Safety).	Brittany Belcher (b) (4)	06 Apr 2021 20:12:30
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:04:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
User opened query ' PV Query: Initial Query response was entered as "updated", yet symptom log in COVID-19 assessments tab, has not been updated.   Please complete the symptoms log in COVID-19 Assessments tab.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:02:04
User closed query 'PV Query: Please complete the symptoms log in COVID-19 Assessments tab. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:02:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:58:18
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:57:33
Query 'PV Query: Please complete the symptoms log in COVID-19 Assessments tab. ' answered with 'updated' (Site from Safety).	Brittany Belcher (b) (4)	05 Apr 2021 20:24:08
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' answered with 'updated' (Site from Safety).	Brittany Belcher (b) (4)	05 Apr 2021 20:23:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated. ' (Site from Safety).	Brittany Belcher (b) (4)	05 Apr 2021 20:23:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Updated' (Site from Safety).	Brittany Belcher (b) (4)	05 Apr 2021 20:23:30
User entered 'SUBJECT REPORTS TO HER UNBLINDING VISIT TODAY AND STATED THAT SHE HAD BEEN HOSPITALIZED ON 22DEC2020 AND DISCHARGED ON 30DEC2020 DU TO COVID-19. SUBJECT SIGNED MEDICAL RECORDS RELEASE FORM AND MEDICAL RECORDS HAVE BEEN REQUESTED. ONCE RECORDS ARE RECEIVED, SAE WILL BE UPDATED PER PROTOCOL.	Brittany Belcher (b) (4)	05 Apr 2021 20:22:44
4/5/2021:Subject's medical records regarding previously reported SAE has been received/reviewed. All Con Meds, Medical History, and Con Procedures lists updated in source and EDC. IRB was updated after review.' reason for change: Data Entry Error		
User opened query 'PV Query: Please complete the symptoms log in COVID-19 Assessments tab.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:54:12
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:53:38
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:53:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:53:22
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:50:53
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:50:50
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:50:48
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' answered with 'waiting on records ' (Site from Safety).	Wendy Taylor (b) (4)	15 Mar 2021 13:36:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'waiting on records ' (Site from Safety).	Wendy Taylor (b) (4)	15 Mar 2021 13:36:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'awaiting records' (Site from Safety).	Wendy Taylor (b) (4)	15 Mar 2021 13:36:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:48:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:47:18
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 18:11:28
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Feb 2021 14:45:16
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Feb 2021 14:45:16
User entered 'Subject reports to her Unblinding visit today and stated that she had been hospitalized on 22DEC2020 and discharged on 30DEC2020 du to Covid-19. Subject signed medical records release form and medical records have been requested. Once records are received, SAE will be updated per protocol.' reason for change: Data Entry Error	Brittany Belcher (b) (4)	02 Feb 2021 14:45:16

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Feb 2021 14:41:56
User entered empty.	Brittany Belcher (b) (4)	02 Feb 2021 14:41:56

**US3302472**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 14:41:56

**US3302472**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 14:41:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query 'Was this AE meant to be placed in EDC for this subject? If so, please complete the AE page, if not, please delete the AE of AEID.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:02:35
Query 'Was this AE meant to be placed in EDC for this subject? If so, please complete the AE page, if not, please delete the AE of AEID.' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	05 Apr 2021 19:36:34
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01
User opened query 'Was this AE meant to be placed in EDC for this subject? If so, please complete the AE page, if not, please delete the AE of AEID.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 21:17:01
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:54:58
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 18:35:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: Appetite disorders, PT: Decreased appetite, LLT: Anorexia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 12:17:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 12:17:49
Data point term sent to Coder	System	05 Apr 2021 19:36:05
User entered 'Endorses Anorexia'	Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
User entered empty.	System	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
User entered '06 Jan 2021' reason for change: Data Entry Error	System	05 Apr 2021 19:36:29
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	Brittany Belcher (b) (4)	05 Apr 2021 19:36:29
User entered '06 Jan 2020'		
DataPoint activated with code reason code Data required.	System	05 Apr 2021 19:36:04
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
User entered empty.	System	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'l'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
User entered '0'	System	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
User entered '1'	System	05 Apr 2021 19:36:04
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:40
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	05 Apr 2021 19:27:09
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	01 Apr 2021 18:51:01

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:21:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:21:53
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	09 Apr 2021 12:47:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:32:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:32:56
Data point term sent to Coder	System	05 Apr 2021 19:38:09
User entered 'Acute Respiratory Failure with Hypoxia'	Brittany Belcher (b) (4) (b) (4) (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
User entered empty.	System	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:48:20
User closed query 'Please review source and revise if needed. Source states that AE ended on 06Jan2021.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 01:48:17
Query 'Please review source and revise if needed. Source states that AE ended on 06Jan2021.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	16 Apr 2021 18:43:35
Signature has been broken.	Brittany Belcher (b) (4)	16 Apr 2021 18:43:26
User entered '06 Jan 2021' reason for change: Data Entry Error	Brittany Belcher (b) (4)	16 Apr 2021 18:43:26
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:07:23
User opened query 'Please review source and revise if needed. Source states that AE ended on 06Jan2021.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:05:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '06 Feb 2021'	Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
User entered empty.	System	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
User closed query 'Per MM: Please review and confirm the severity. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 07:52:43
Query 'Per MM: Please review and confirm the severity. ' answered with 'Per source/ Sub-I and PI review, data entered is correct.' (Site from DM).	Brittany Belcher (b) (4)	23 Apr 2021 12:02:29
User opened query 'Per MM: Please review and confirm the severity. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 11:42:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
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	05 Apr 2021 19:37:29
User entered 'No (N)' reason for change: Data Entry Error	System	05 Apr 2021 19:37:29
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:37:22
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'l'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:37:22

**US3302472**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:57:13**

**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
User entered '0'	System	05 Apr 2021 19:37:29

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24
User entered 'I'	System	05 Apr 2021 19:37:22

US3302472

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:18:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 19:00:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 19:00:04
Data point term sent to Coder	System	15 Apr 2021 18:57:30
User entered 'COPD Exacerbation'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User entered empty.	System	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '06 Jan 2021'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User entered empty.	System	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'Not Related (NOT RELATED)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'Not Applicable (NOT APPLICABLE)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'l'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:03:58
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User entered '0'	System	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

US3302472

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
User entered '1'	System	15 Apr 2021 18:57:23
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:06
DataPoint activated with code reason code Data required.	Brittany Belcher (b) (4)	15 Apr 2021 18:56:27
DataPoint inactivated with code reason code Data not required.	Brittany Belcher (b) (4)	05 Apr 2021 19:34:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:57:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:48
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:50:17
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 02:08:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:06:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:06:13
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 20:39:24
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 20:39:17
Coding entries removed.	Brittany Belcher (b) (4)	15 Apr 2021 20:39:17
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 20:39:17
User entered 'ALBUTEROL (90mcg)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 20:39:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:08:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Brittany Belcher (b) (4) (b) (4) (b) (4)	29 Oct 2020 17:08:42  29 Oct 2020 17:07:44 29 Oct 2020 17:07:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 15:15:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'albuterol'	Coder Import (b) (4) (b) (4) System Brittany Belcher (b) (4) (b) (4) (b) (4)	12 Oct 2020 15:15:22  12 Oct 2020 15:14:28 12 Oct 2020 15:13:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Emphysema' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 17:07:10
User entered 'asthma'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 02:08:00
User closed query 'Per medical records, the dose per administration is documented as 2 Puff Kindly move the 90ug to the name of the medication. Please review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 02:07:57
Query 'Per medical records, the dose per administration is documented as 2 Puff Kindly move the 90ug to the name of the medication. Please review the medical records, and update accordingly. ' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	15 Apr 2021 20:40:04
User entered '2' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 20:39:17
User opened query 'Per medical records, the dose per administration is documented as 2 Puff Kindly move the 90ug to the name of the medication. Please review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:52:47
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 18:59:47
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 16:25:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '90'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 02:08:02
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 20:39:17
User entered 'puff (PUFF)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 20:39:17
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 16:25:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'ug (ug)'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:28:53
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
Signature has been broken.	(b) (4) Brittany Belcher (b) (4)	15 Apr 2021 18:59:53
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un UNK 2000'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:35:16
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:13:47

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:13:47

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:13:47

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:13:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:08:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:08:43
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 17:07:45
Coding entries removed.	Brittany Belcher (b) (4)	29 Oct 2020 17:07:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:15:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:15:23
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 15:14:28
User entered 'symbicort'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Emphysema' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 17:07:26
User entered 'asthma'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '160/4.5'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'ug (ug)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)  	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un UNK 2010'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:22

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Oct 2020 15:14:22

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 15:14:22

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 15:14:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, PRODUCTSYNONYM: FARXIGA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:16:35
Data point term sent to Coder	System	12 Oct 2020 15:15:30
User entered 'farxiga'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'diabetes type 2'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '5'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un Jan 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:53:01
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:01:36
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:01:36
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:01:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:53:21
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:01:36
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:01:36
User entered '22 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:01:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:14:47

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User entered '1'	System	12 Oct 2020 15:14:47

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User entered '1'	System	12 Oct 2020 15:14:47

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:26
User entered '804 (804)'	System	12 Oct 2020 15:14:47

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:16:35
Data point term sent to Coder User entered 'prolia'	System	12 Oct 2020 15:15:30
	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'osteoporosis'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '60'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)  (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)  	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per CDM CLR re-query: Thank you for your answer. However, according to a entered data this medication is given more than just once. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 11:22:57
Query 'Per CDM CLR re-query: Thank you for your answer. However, according to a entered data this medication is given more than just once. Please review and update or clarify otherwise. Thank you!' answered with 'information is correct per source' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:22:02
User opened query 'Per CDM CLR re-query: Thank you for your answer. However, according to a entered data this medication is given more than just once. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:50:14
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:49:35
Query 'Per DM CLR: Please review frequency as this brittany cooksey was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. ' answered with 'given one time' (Site from DM).	(b) (4) (b) (4)	08 Dec 2020 20:46:53
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:04:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un Jul 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:25

**US3302472**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:15:25

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:15:25

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:15:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:30:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:30:55
Data point term sent to Coder Coding entries removed.	System brittany cooksey (b) (4)	08 Dec 2020 20:48:35 08 Dec 2020 20:48:06
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:17:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:17:22
Data point term sent to Coder User entered 'lasix'	System Brittany Belcher (b) (4)	12 Oct 2020 15:16:31 12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:09:54
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Edema (arms, legs, etc.; Pulmonary, Cerebral, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 07:50:47
Query 'Per DM CLR: Please update the condition to include the type and/or location of Edema (arms, legs, etc.; Pulmonary, Cerebral, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 20:48:14
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 20:48:06
User entered 'EDEMA - bilateral upper and lower extremities' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 20:48:06
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Edema (arms, legs, etc.; Pulmonary, Cerebral, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:04:35
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'edema'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '40'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:36:07
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:19
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:19
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:02:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:36:05
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:19
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:19
User entered '22 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:02:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:15:51

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User entered '1'	System	12 Oct 2020 15:15:51

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User entered '1'	System	12 Oct 2020 15:15:51

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:08
User entered '804 (804)'	System	12 Oct 2020 15:15:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: IVABRADINE HYDROCHLORIDE, PRODUCTSYNONYM: CORLANOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 20:50:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 20:50:46
Data point term sent to Coder Coding entries removed.	System brittany cooksey (b) (4)	08 Dec 2020 20:49:38 08 Dec 2020 20:49:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: IVABRADINE HYDROCHLORIDE, PRODUCTSYNONYM: CORLANOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:17:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:17:22
Data point term sent to Coder User entered 'Corlanor'	System Brittany Belcher (b) (4)	12 Oct 2020 15:16:31 12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:14:09
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per CDM CLR re-query: Thank you for your answer. Please consider adding "Chest pain - UNK" under Medical History form because start date is UN UNK 2019 or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 08:18:49
Query 'Per CDM CLR re-query: Thank you for your answer. Please consider adding "Chest pain - UNK" under Medical History form because start date is UN UNK 2019 or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	25 Jan 2021 20:21:37
User opened query 'Per CDM CLR re-query: Thank you for your answer. Please consider adding "Chest pain - UNK" under Medical History form because start date is UN UNK 2019 or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:37:17
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:37:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'taken prior to icf' (Site from DM).	brittany cooksey (b) (4)	22 Jan 2021 20:36:33
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:37:02

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:50:57
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'unk' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 20:49:46
DataPoint Un-verified.	(b) (4)	08 Dec 2020 20:49:22
User entered 'CHEST PAIN - unk' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 20:49:22
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:05:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'chest pain'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '7.5'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:36:25
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:08:27
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:08:27
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:08:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:36:27
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:08:27
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:08:27
User entered '22 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:08:27
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:16:18

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User entered '2'	System	12 Oct 2020 15:16:18

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User entered '1'	System	12 Oct 2020 15:16:18

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:10
User entered '804 (804)'	System	12 Oct 2020 15:16:18

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:08:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:08:43
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 17:07:44
Coding entries removed.	Brittany Belcher (b) (4)	29 Oct 2020 17:06:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:18:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:18:17
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 15:17:31
User entered 'singulair'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Emphysema' reason for change: Data Entry Error	Brittany Belcher (b) (4)	29 Oct 2020 17:06:55
User entered 'asthma'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '10'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)  (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)  	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un Mar 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:07

**US3302472**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 15:17:07

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 15:17:07

**US3302472**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 15:17:07

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 20:52:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 20:52:13
Data point term sent to Coder Coding entries removed.	System brittany cooksey (b) (4)	08 Dec 2020 20:50:43 08 Dec 2020 20:50:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 16:13:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 16:13:33
Data point term sent to Coder Coding entries removed.	System Brittany Belcher (b) (4)	20 Nov 2020 13:05:22 20 Nov 2020 13:04:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:19:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:19:27
Data point term sent to Coder	System	12 Oct 2020 15:18:33
User entered 'xarelto'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:14:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 09:36:03
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	22 Jan 2021 20:37:01
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	22 Jan 2021 20:36:54
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	22 Jan 2021 20:36:54
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:40:38
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:46:59
DataPoint Un-verified.	Brittany Belcher (b) (4)	20 Nov 2020 13:04:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	20 Nov 2020 13:04:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:14:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH #19 CAD (CORONARY ARTERY DISEASE) recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:54:47
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH #19 CAD (CORONARY ARTERY DISEASE) recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 20:50:36
DataPoint Un-verified.	brittany cooksey (b) (4)	08 Dec 2020 20:50:27
User entered 'CAD' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 20:50:27
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH #19 CAD (CORONARY ARTERY DISEASE) recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:39:33
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:47:01
DataPoint Un-verified.	Brittany Belcher (b) (4)	20 Nov 2020 13:04:25
User entered 'Cardiac Prophylaxis' reason for change: Data Entry Error	Brittany Belcher (b) (4)	20 Nov 2020 13:04:25
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User entered 'blood thinner'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '20'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 02:11:49
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:05:50
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:05:50
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:05:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 02:11:52
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:05:50
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:05:50
User entered '22 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:05:50
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:17:32

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User entered '1'	System	12 Oct 2020 15:17:32

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User entered '1'	System	12 Oct 2020 15:17:32

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:45
User entered '804 (804)'	System	12 Oct 2020 15:17:32

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:19:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:19:27
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 15:18:33
User entered 'crestor'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'hypercholesterolemia'	Brittany Belcher (b) (4)  	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '40'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un Mar 2020'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 15:18:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 15:18:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 15:18:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:15:53
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTSYNONYM: ENTRESTO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 08:11:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 08:11:09
Data point term sent to Coder	System	08 Dec 2020 20:52:45
DataPoint Un-verified.	brittany cooksey (b) (4)	08 Dec 2020 20:52:03
Coding entries removed.	brittany cooksey (b) (4)	08 Dec 2020 20:52:03
User entered 'ENTRESTO (sacubitril/valsartan)' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 20:52:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTSYNONYM: ENTRESTO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 16:13:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 16:13:33
Data point term sent to Coder	System	20 Nov 2020 13:06:22

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Brittany Belcher (b) (4)	20 Nov 2020 13:05:44
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTS YNOM: ENTRESTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:19:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:19:27
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 15:18:33
User entered 'entresto'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:16:00
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Un-verified.	(b) (4)	
	Brittany Belcher (b) (4)	20 Nov 2020 13:05:44
User entered 'CAD (Coronary Artery Disease)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	20 Nov 2020 13:05:44
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'heart attack'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:15:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Query 'Per CDM CLR re-query: Thank you for your answer. Please review if entered dosages are correct because 49/51 are unusual dosages. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:52:50
User opened query 'Per CDM CLR re-query: Thank you for your answer. Please review if entered dosages are correct because 49/51 are unusual dosages. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:52:34
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:51:41
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 20:52:12
DataPoint Un-verified.	brittany cooksey (b) (4)	08 Dec 2020 20:52:03
User entered '49/51' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 20:52:03
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:07:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '49'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'twice daily (BID)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'un UNK 2019'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 02:12:34
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:38
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:38
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:02:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 02:12:36
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:38
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:02:38
User entered '22 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:02:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:18:31

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User entered '2'	System	12 Oct 2020 15:18:31

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User entered '1'	System	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:01
User entered '804 (804)'	System	12 Oct 2020 15:18:31

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
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)	29 Oct 2020 19:56:06
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Oct 2020 19:56:06
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Oct 2020 19:11:04
User entered 'Tylenol'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:53:03
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'this is during 7 day post doe ediairy. This is a solicited AR' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 21:32:14
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:41:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'injection pain'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '500'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'mg (mg)'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '14 Oct 2020'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '0'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered '14 Oct 2020'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 19:10:59

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User entered empty.	System	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User entered empty.	System	28 Oct 2020 19:10:59

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:05
User entered empty.	System	28 Oct 2020 19:10:59

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:24:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN, PRODUCTSYNONYM: O2 [OXYGEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 10:03:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 10:03:53
Data point term sent to Coder	System	05 Apr 2021 19:39:19
User entered 'O2'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:24:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:24:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:24:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '2'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:00
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:05
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Liters'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Continuous'	(b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:35
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '06 Jan 2021'	(b) (4)	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:25:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:39:04

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
User entered empty.	System	05 Apr 2021 19:39:04

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
User entered empty.	System	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:12
User entered empty.	System	05 Apr 2021 19:39:04

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
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)	05 Apr 2021 19:40:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:40:52
Data point term sent to Coder	System	05 Apr 2021 19:40:20
User entered 'Tylenol'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:25
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:29
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Pain at injection site'	(b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:32
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '500'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:38
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:42
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '02 Feb 2021'	(b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:52
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '02 Feb 2021'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:26:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:40:16

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
User entered empty.	System	05 Apr 2021 19:40:16

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
User entered empty.	System	05 Apr 2021 19:40:16

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:19
User entered empty.	System	05 Apr 2021 19:40:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:32
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
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)	05 Apr 2021 19:42:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:42:33
Data point term sent to Coder	System	05 Apr 2021 19:41:24
User entered 'Tylenol'	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:38
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '650'	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:41
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:50
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:52
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:29:57
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:30:00
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '30 Dec 2020'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 13:30:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:41:09

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
User entered empty.	System	05 Apr 2021 19:41:09

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
User entered empty.	System	05 Apr 2021 19:41:09

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:34
User entered empty.	System	05 Apr 2021 19:41:09

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:40:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:20:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:13:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:13:50
Data point term sent to Coder	System	05 Apr 2021 19:44:31
User entered 'Sodium Chloride (0.9% bolus premix)'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:40:11
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:40:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:40:08
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '1,000'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:40:06
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mL (mL)'	(b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:47
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:42
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:16

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
User entered empty.	System	05 Apr 2021 19:44:16

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
User entered empty.	System	05 Apr 2021 19:44:16

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:31
User entered empty.	System	05 Apr 2021 19:44:16

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:26
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:47:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:47:26
Data point term sent to Coder	System	05 Apr 2021 19:46:36
Data point term sent to Coder	System	05 Apr 2021 19:45:32
User entered 'Albuterol Nebulizer'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:28
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:29
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	(b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
User closed query ' Per medical records the dose per administration is documented as 10 mg. Kindly review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 00:59:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:59:12
Query ' Per medical records the dose per administration is documented as 10 mg. Kindly review the medical records, and update accordingly. ' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:38:54
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:37:21
User entered '10' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:37:21
User opened query ' Per medical records the dose per administration is documented as 10 mg. Kindly review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:18:18
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '2.5/'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:59:17
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:37:39
User entered 'mg (mg)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:37:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:46:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 19:46:13
User entered 'Other (OTHER)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:44:44
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:59:26
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:37:39
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:37:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered 'mg/ml' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:59:30
User closed query ' Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 00:59:28
Query ' Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:39:09
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:37:21
User entered 'other (OTHER)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:37:21
User opened query ' Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:17:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:46:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 19:46:13
User entered 'once (ONCE)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:44:44
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:59:32
DataPoint Un-verified.	Brittany Belcher (b) (4)	14 Apr 2021 19:37:21
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:37:21
User entered 'continuous' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:18
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:19:13
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:46:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 19:46:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:44:44
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:52
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	05 Apr 2021 19:46:13
User entered '22 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	05 Apr 2021 19:44:44
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 19:46:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 19:46:13
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:44:44
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:18:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 19:46:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 19:46:13
User entered 'No (N)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	05 Apr 2021 19:46:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:44:44
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:44:44

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User entered empty.	System	05 Apr 2021 19:44:44

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User entered empty.	System	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:45
User entered empty.	System	05 Apr 2021 19:44:44

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:09
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:52:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:52:51
Data point term sent to Coder	System	05 Apr 2021 19:47:37
User entered 'Vancomycin'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:11
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:00:02
User closed query ' Per medical records the dose per administration is documented as 1,500 mg. Kindly review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 00:59:58
Query ' Per medical records the dose per administration is documented as 1,500 mg. Kindly review the medical records, and update accordingly. ' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:40:28
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:40:11
User entered '1,500' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:40:11
User opened query ' Per medical records the dose per administration is documented as 1,500 mg. Kindly review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:25:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '25'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:00:07
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:40:11
User entered 'mg (mg)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:40:11
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:00:26
User closed query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:00:24
Query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly. ' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:40:44
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:40:11
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:40:11
User opened query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:26:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg/kg X 60.8kg'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:50
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:00
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:01
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:05
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:03
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:47:29

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
User entered empty.	System	05 Apr 2021 19:47:29

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
User entered empty.	System	05 Apr 2021 19:47:29

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:18
User entered empty.	System	05 Apr 2021 19:47:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:05
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:49:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:49:31
Data point term sent to Coder	System	05 Apr 2021 19:48:38
User entered 'Ibuprofen'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:06
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:08
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '600'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:19
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:35
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:47
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:17:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:12

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
User entered empty.	System	05 Apr 2021 19:48:12

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
User entered empty.	System	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:24
User entered empty.	System	05 Apr 2021 19:48:12

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:13
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:50:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:50:22
Data point term sent to Coder	System	05 Apr 2021 19:49:39
User entered 'Acetaminophen'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:23
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:26
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'COvid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:35
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '1,000'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:38
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:42
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:50
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:21:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
User entered empty.	System	05 Apr 2021 19:48:49

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
User entered empty.	System	05 Apr 2021 19:48:49

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:42:17
User entered empty.	System	05 Apr 2021 19:48:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:31:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:31:59
Data point term sent to Coder	System	05 Apr 2021 19:49:39
User entered 'Methylprednisolone'	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:24
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:23
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '80'	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:19
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:11
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:09
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:06
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:04
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:00
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:22:57
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:49:29

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
User entered empty.	System	05 Apr 2021 19:49:29

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
User entered empty.	System	05 Apr 2021 19:49:29

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:44
User entered empty.	System	05 Apr 2021 19:49:29

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:55:59
User closed query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly. Please make sure to select save because the update did not occur.	(b) (4), (b) (6)	16 Apr 2021 14:45:26
' (Site from CRA).		
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Apr 2021 02:00:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	16 Apr 2021 02:00:29
Data point term sent to Coder	System	15 Apr 2021 15:59:47
Query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly. Please make sure to select save because the update did not occur.	Brittany Belcher (b) (4)	15 Apr 2021 15:59:46
' answered with 'updated.' (Site from CRA).		
Coding entries removed.	Brittany Belcher (b) (4)	15 Apr 2021 15:59:30
User entered 'IPrATROPIUM' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 15:59:30
User opened query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly. Please make sure to select save because the update did not occur.	(b) (4), (b) (6)	15 Apr 2021 12:23:35
' (Site from CRA).		

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 12:23:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 06:07:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 06:07:01
Data point term sent to Coder	System	14 Apr 2021 19:42:51
Query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly.' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:42:45
Coding entries removed.	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
User entered 'IPATROPIUM' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
User opened query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:51:20
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:26:55

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	06 Apr 2021 12:26:55
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Apr 2021 19:50:40
User entered 'Ipratropium (0.02%/1mg)'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:27
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Emphysema'	(b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:56:11
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:18:01
User entered '1,000' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:18:01
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered '1'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:56:15
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:18:01
User entered 'ug (ug)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:18:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:01:47
User closed query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:01:45
Query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly. ' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:43:01
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
User entered 'mg (mg)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
User opened query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:35:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'puff (PUFF)'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:33
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:01:53
User closed query 'Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:01:51
Query 'Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:43:15
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
User entered 'other (OTHER)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
User opened query 'Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:53:20
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:01:56
DataPoint Un-verified.	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
User entered 'Continuous' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:42:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:08
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:06
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:17
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:18
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:20
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:22
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:23
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:50:21

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User entered empty.	System	05 Apr 2021 19:50:21

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User entered empty.	System	05 Apr 2021 19:50:21

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:51
User entered empty.	System	05 Apr 2021 19:50:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:28
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:28:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 19:51:42
User entered 'Lactated Ringers (Infusion Premix)'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:50
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:52
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '1,000'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mL (mL)'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:01
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:03
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:05
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:08
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:51:05

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
User entered empty.	System	05 Apr 2021 19:51:05

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
User entered empty.	System	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:12
User entered empty.	System	05 Apr 2021 19:51:05

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 02:00:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 02:00:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:35:02
User closed query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly. Please make sure to select save because the update did not occur. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:34:44
Query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly. Please make sure to select save because the update did not occur. ' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	15 Apr 2021 16:33:30
Data point term sent to Coder Coding entries removed.	System	15 Apr 2021 16:33:26
	Brittany Belcher (b) (4)	15 Apr 2021 16:33:05
User entered 'IPrATROPIUM' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 16:33:05
User opened query 'Per medical records, the name of the medication is documented as " Ipratropium." Kindly review the medical records, and update accordingly. Please make sure to select save because the update did not occur. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 12:21:11

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per medical records the name of the medication is documented as " Ipratropium". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 12:21:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 06:07:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 06:07:02
Data point term sent to Coder	System	14 Apr 2021 19:45:08
Query 'Per medical records the name of the medication is documented as " Ipratropium". Kindly review the medical records, and update accordingly.' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:44:54
Coding entries removed.	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User entered 'IPATROPIUM' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User opened query 'Per medical records the name of the medication is documented as " Ipratropium". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:28:09
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:25:54

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	06 Apr 2021 12:25:54
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Apr 2021 19:53:44
User entered 'Ipatropium (0.02%)'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:37:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:37:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Emphysema'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
	(b) (4)	
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:35:15
	(b) (4)	
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:18:54
	(b) (4)	
User entered '1,000' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:18:54
	(b) (4)	
Query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly.	(b) (4), (b) (6)	14 Apr 2021 18:34:19
' canceled (Site from CRA).	(b) (4), (b) (6)	
User opened query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly.	(b) (4), (b) (6)	14 Apr 2021 18:33:17
' (Site from CRA).	(b) (4)	
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered '1'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48
	(b) (4)	

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:33
User closed query 'Per source the dose unit is listed as mL. Kindly review the source, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:34:15
Query 'Per source the dose unit is listed as mL. Kindly review the source, and update accordingly.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	16 Apr 2021 18:46:07
User entered 'mL (mL)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	16 Apr 2021 18:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:49:09
User opened query 'Per source the dose unit is listed as mL. Kindly review the source, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:49:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:35:28
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:18:54
User entered 'ug (ug)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:18:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:02:38
User closed query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:02:36
Query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:45:10
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User opened query ' Per medical records the dose unit is documented as mg. Please review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:34:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Other (OTHER)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:35:43
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered 'vial'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:02:43
User closed query 'Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:02:41
Query 'Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' answered with 'updated.' (Site from CRA).	Brittany Belcher (b) (4)	14 Apr 2021 19:45:24
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User entered 'other (OTHER)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User opened query 'Per medical records- frequency is documented as "continuous". Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 18:33:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	06 Apr 2021 20:30:13
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	06 Apr 2021 20:30:13
User entered 'once daily (QD)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	06 Apr 2021 20:30:13
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	05 Apr 2021 19:52:48
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:02:45
DataPoint Un-verified.	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
Signature has been broken.	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
User entered 'continuous' reason for change: Data Entry Error	Brittany Belcher (b) (4)	14 Apr 2021 19:44:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:41:18
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:41:16
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:40:00
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:40:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '22 Dec 2020'	(b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:57
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '23 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:39:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	14 Apr 2021 19:44:37
User entered '1'	System	06 Apr 2021 20:30:13
User entered empty.	System	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	14 Apr 2021 19:44:37
User entered 'I'	System	06 Apr 2021 20:30:13
User entered empty.	System	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	14 Apr 2021 19:44:37
User entered '804 (804)'	System	06 Apr 2021 20:30:13
User entered empty.	System	05 Apr 2021 19:52:48

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:09
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:52:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:52:51
Data point term sent to Coder	System	05 Apr 2021 19:53:46
User entered 'Vancomycin'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '750'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:16
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:57:46
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	15 Apr 2021 18:59:25
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 18:59:25
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 18:59:25
User entered 'other (OTHER)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 18:59:25
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). DataPoint Verified.	System	15 Apr 2021 18:58:50
User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 18:38:19
User entered 'once (ONCE)'	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:57:51
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 18:59:25
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 18:59:25
User entered 'Once @ 125ml/ hour over 120 min' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 18:59:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:20
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:22
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:29
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:32
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '23 Dec 2020'	(b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:57:59
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 18:58:50
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 18:58:50
User entered '25 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 18:58:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:38
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered '23 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:38:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:53:27

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User entered empty.	System	05 Apr 2021 19:53:27

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User entered empty.	System	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User entered empty.	System	05 Apr 2021 19:53:27

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:19
User closed query 'Monitor is unable to verify this entry. Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:51:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Apr 2021 01:09:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Apr 2021 01:09:07
Data point term sent to Coder	System	15 Apr 2021 20:37:23
Coding entries removed.	Brittany Belcher (b) (4)	15 Apr 2021 20:37:05
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 20:37:05
User entered 'ALBUTEROL NEBULIZER (2.5mg/3ml)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 20:37:05
Query 'Monitor is unable to verify this entry. Kindly review the medical records, and update accordingly.' answered with 'In the medical records, it is under the Hospital Medication Detail. It is also noted under: "Orders- General Information"... Per medical records, this med was ordered on 12/22/2020 @ 18:34 ' (Site from CRA).	Brittany Belcher (b) (4)	15 Apr 2021 16:36:26
User opened query 'Monitor is unable to verify this entry. Kindly review the medical records, and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 01:46:35

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 10:22:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 10:22:51
Data point term sent to Coder	System	05 Apr 2021 19:55:48
User entered 'Albuterol Nebulizer'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:22
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:24
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Emphysema'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:26
User closed query 'Kindly provide the correct dose per administration. Please move 2.5mg/3mL and document it with the name of the medication.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:51:16
Query 'Kindly provide the correct dose per administration. Please move 2.5mg/3mL and document it with the name of the medication.' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	15 Apr 2021 20:37:21
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 20:37:05
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 20:37:05
User opened query 'Kindly provide the correct dose per administration. Please move 2.5mg/3mL and document it with the name of the medication.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:55:28
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '2.5/3'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:28
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:29
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 20:37:05
User entered 'Vial' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 20:37:05
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered 'mg/ml'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:31
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:51
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 01:24:23
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:37
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:51:54
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 01:24:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:07
User closed query 'Kindly verify the start and end date' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:51:57
Query 'Kindly verify the start and end date' answered with 'Frequency is once. Start and end date is the same 23DEC2020. ' (Site from CRA).	Brittany Belcher (b) (4)	15 Apr 2021 20:38:09
User opened query 'Kindly verify the start and end date' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:55:56
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 01:24:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered '23 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:10
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 01:24:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:31
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:12
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 01:24:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 01:24:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:22
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '23 Dec 2020'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:52:17
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 01:24:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:20
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 19:54:50

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User entered empty.	System	05 Apr 2021 19:54:50

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User entered empty.	System	05 Apr 2021 19:54:50

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User entered empty.	System	05 Apr 2021 19:54:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:18
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:57:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:57:31
Data point term sent to Coder	System	05 Apr 2021 19:56:49
User entered 'Remdesivir'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:16
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:13
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '200'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:11
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:09
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:05
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:03
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Once @ 500ml/hr over 30 min'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '24 Dec 2020'	(b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:47
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '24 Dec 2020'	(b) (4)	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:41:41
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
User entered empty.	System	05 Apr 2021 19:56:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
User entered empty.	System	05 Apr 2021 19:56:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:40
User entered empty.	System	05 Apr 2021 19:56:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:59:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:59:04
Data point term sent to Coder	System	05 Apr 2021 19:57:50
User entered 'Ascorbic Acid'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:04
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:28
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '500'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:37
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:41
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'q 6 hours'	(b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '24 Dec 2020'	(b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:47
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:50
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '24 Dec 2020'	(b) (4)	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:44:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:56:50

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
User entered empty.	System	05 Apr 2021 19:56:50

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
User entered empty.	System	05 Apr 2021 19:56:50

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:47
User entered empty.	System	05 Apr 2021 19:56:50

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:48:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:20:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:14:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:14:55
Data point term sent to Coder	System	05 Apr 2021 19:58:51
User entered 'Sodium Chloride (0.9% Infusion)'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:48:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:49:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:49:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '100'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:49:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mL (mL)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:50:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:50:35
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:50:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:16
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:29
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '24 Dec 2020'	(b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:52:09
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '24 Dec 2020'	(b) (4)	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:52:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 19:58:21

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
User entered empty.	System	05 Apr 2021 19:58:21

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
User entered empty.	System	05 Apr 2021 19:58:21

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:43
User entered empty.	System	05 Apr 2021 19:58:21

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:52:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:52:51
Data point term sent to Coder	System	05 Apr 2021 20:01:08
User entered 'Vancomycin'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:16
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:18
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:20
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '1,000'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:53:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:54:01
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '26 Dec 2020'	(b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:54:03
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:54:04
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:54:06
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '26 Dec 2020'	(b) (4)	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:54:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:03

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
User entered empty.	System	05 Apr 2021 20:00:03

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
User entered empty.	System	05 Apr 2021 20:00:03

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:45
User entered empty.	System	05 Apr 2021 20:00:03

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
User coded data point as ATC: VARIOUS, ATC: DIAGNOSTIC AGENTS, ATC: OTHER DIAGNOSTIC AGENTS, ATC: TUBERCULOSIS DIAGNOSTICS, PRODUCT: TUBERCULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 12:57:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 12:57:50
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 19:00:48
Coding entries removed.	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: DIAGNOSTIC AGENTS, ATC: OTHER DIAGNOSTIC AGENTS, ATC: TUBERCULOSIS DIAGNOSTICS, PRODUCT: TUBERCULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:54:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:54:40
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 20:01:01
User entered 'Tuberculin Injection'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:19
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:54:32
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
User entered 'TB Skin Test' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:20
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:25
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '5'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:27
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'IU (IU)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:29
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:31
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once (ONCE)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:33
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:54:16
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
User entered 'Transdermal (TRANSDERMAL)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:54:19
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:00:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:41
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered 'Intradermal'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '28 Dec 2020'	(b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '28 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:55:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:00:58

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
User entered empty.	System	05 Apr 2021 20:00:58

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
User entered empty.	System	05 Apr 2021 20:00:58

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
User entered empty.	System	05 Apr 2021 20:00:58

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:05
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:04:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:04:30
Data point term sent to Coder	System	05 Apr 2021 20:03:11
User entered 'Remdesivir'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:09
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '100'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:16
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:31
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:32
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'q 24 hours variable @ 500ml/hr over 30 min'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Intravenous (INTRAVENOUS)'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:37
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '25 Dec 2020'	(b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:41
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '28 Dec 2020'	(b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:57:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
User entered empty.	System	05 Apr 2021 20:02:15

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
User entered empty.	System	05 Apr 2021 20:02:15

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:15
User entered empty.	System	05 Apr 2021 20:02:15

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 07:55:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:55:22
Data point term sent to Coder	System	05 Apr 2021 20:04:13
User entered 'Furosemide'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:19
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Edema (Bilateral Upper and lower Extremities)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:22
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '20'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:32
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:42
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:47
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '03 Jan 2020'	(b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:52
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '30 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:04:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:03:43

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
User entered '1'	System	05 Apr 2021 20:03:43

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
User entered '1'	System	05 Apr 2021 20:03:43

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:21
User entered '804 (804)'	System	05 Apr 2021 20:03:43

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:41:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:06:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:06:32
Data point term sent to Coder	System	05 Apr 2021 20:05:14
User entered 'Ascorbic Acid'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:41:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:41:57
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:41:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '500'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:01
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	(b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:02
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:04
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:06
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'q 6 hours'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:13
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '24 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:19
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '30 Dec 2020'	(b) (4)	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:42:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:20

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
User entered empty.	System	05 Apr 2021 20:04:20

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
User entered empty.	System	05 Apr 2021 20:04:20

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:29
User entered empty.	System	05 Apr 2021 20:04:20

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:24
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:06:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:06:32
Data point term sent to Coder	System	05 Apr 2021 20:05:14
User entered 'Vitamin D3'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:26
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:28
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '5,000'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:32
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'IU (IU)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:33
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:36
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:37
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '30 Dec 2020'	(b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:52
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '06 Jan 2021'	(b) (4)	
	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:40:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:04:56

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
User entered '1'	System	05 Apr 2021 20:04:56

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
User entered '1'	System	05 Apr 2021 20:04:56

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:39
User entered '804 (804)'	System	05 Apr 2021 20:04:56

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:10:24
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:06:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:06:33
Data point term sent to Coder	System	05 Apr 2021 20:06:15
User entered 'Dexamethasone'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:10:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:11:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Covid-19'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:14:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '6'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:16:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg (mg)'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:16:50
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:16:53
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:16:55
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:16:57
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Oral (ORAL)'	(b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:16:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:17:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '30 Dec 2020'	(b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:17:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:17:11
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:59:29
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	15 Apr 2021 19:05:31
User entered '31 Dec 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:05:31
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	15 Apr 2021 19:04:41
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:04:41
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:04:41
User entered '31 Dec 2021' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:04:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:17:29
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered '06 Jan 2021'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:17:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	Brittany Belcher (b) (4)	05 Apr 2021 20:06:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
User entered '1'	System	05 Apr 2021 20:06:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
User entered '1'	System	05 Apr 2021 20:06:00

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:44
User entered '804 (804)'	System	05 Apr 2021 20:06:00

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:27:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 09:58:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:58:37
Data point term sent to Coder	System	05 Apr 2021 20:07:16
User entered 'Nicotine'	Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:27:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:27:39
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Smoking Cessation'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:27:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '21/24'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:07
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Other (OTHER)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'mg/hr'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:12
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once daily (QD)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:17
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Transdermal (TRANSDERMAL)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:19
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:22
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '30 Dec 2020'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:24
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:26
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 01:59:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:28:28
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:07:10

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:07:10

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:07:10

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 20:07:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:08
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:09:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:09:36
Data point term sent to Coder User entered 'Diclofenac'	System Brittany Belcher (b) (4)	05 Apr 2021 20:08:20 05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:10
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:14
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Osteoarthritis'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'I'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:38
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Other (OTHER)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '%'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:42
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'every other day (QOD)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:44
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Topical (TOPICAL)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:49
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:57:28
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:25:36
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:25:36
User entered 'un UNK 2010' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:25:36
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:51
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered '30 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:52
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:54
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:56
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:29:58
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:08:10

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:08:10

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Apr 2021 20:08:10

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 20:08:10

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:21
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:54:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:54:41
Data point term sent to Coder	System	05 Apr 2021 20:09:32
User entered 'Tiotropium Bromide (25mcg)'	Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:23
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:25
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Emphysema'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:27
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '2'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:29
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'puff (PUFF)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:30
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:32
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'once daily (QD)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:34
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:37
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:40
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:58:33
DataPoint Un-verified.	Brittany Belcher (b) (4)	15 Apr 2021 19:26:53
Signature has been broken.	Brittany Belcher (b) (4)	15 Apr 2021 19:26:53
User entered 'un UNK 2017' reason for change: Data Entry Error	Brittany Belcher (b) (4)	15 Apr 2021 19:26:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:41
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
	(b) (4)	
User entered '30 Dec 2020'	Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:43
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered '0'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:45
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:46
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered empty.	(b) (4)	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 01:34:48
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	05 Apr 2021 20:09:25

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:09:25

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:09:25

**US3302472**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 20:09:25

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:58:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 19:15:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 19:15:49
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 19:14:22
User entered 'Xarelto'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:58:59
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:02
User entered 'CAD'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:05
User entered '20'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:07
User entered 'mg (mg)'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:09
User entered empty.	Brittany Belcher (b) (4)  (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:12
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:14
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:16
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:18
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:20
User entered '03 Jan 2021'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:24
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:26
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:30
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:33
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 19:13:45

**US3302472**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 19:13:45

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 19:13:45

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 19:13:45

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR [SALBUTAMOL SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 09:28:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 09:28:48
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 19:22:37
User entered 'ProAir'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:56
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:58
User entered 'Emphysema'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:00:03
User entered '90'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:00:05
User entered 'ug (ug)'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:00:08
User entered empty.	Brittany Belcher (b) (4)  (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:00:20
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:00:24
User entered empty.	Brittany Belcher (b) (4)  	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:00:26
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:00:28
User entered empty.	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:00:30
User entered '22 Dec 2020'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:00:33
User entered '0'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:06:55
User entered 'Yes (Y)'	Brittany Belcher (b) (4)  (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:06:57
User entered empty.	Brittany Belcher (b) (4)  (b) (4)	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:06:59
User closed query 'Per medical records, the subject received 1,884.8mL of sodium chloride on 12/22/2020- 12/22/2020. Kindly review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:06:53
Query 'Per medical records, the subject received 1,884.8mL of sodium chloride on 12/22/2020- 12/22/2020. Kindly review the medical records, and update accordingly. ' answered with 'Per medical records, the dose administered to subject on 22DEC2020 was 1,000ml beginning @ 20:15 through 21:10 (page 1 of 4; MARS, Sodium Chloride 0.9% bolus Premix)' (Site from CRA).	Brittany Belcher (b) (4)	15 Apr 2021 20:45:24
User opened query 'Per medical records, the subject received 1,884.8mL of sodium chloride on 12/22/2020- 12/22/2020. Kindly review the medical records, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 20:02:14
User entered 'No (N)'	Brittany Belcher (b) (4)	15 Apr 2021 19:21:49

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 16:57:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:21:49

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:21:49

US3302472

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 16:57:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:21:49

US3302472

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:57:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:50:08
User entered 'No (N)'	Brittany Belcher (b) (4)	12 Oct 2020 15:20:02

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'USA-US087-2021-MRNA-1273-P301000017'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Gregory'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Feldman'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '141 Harold Fleming Court'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Spartanburg'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '29303'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'US'	System	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Apr 2021 14:43:09
User entered '3'	System	06 Apr 2021 14:04:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
User entered '2'	System	16 Feb 2021 19:00:49
User entered '1'	System	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'USA-US087-2021-MRNA-1273-P301000017'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Gregory'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Feldman'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '141 Harold Fleming Court'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Spartanburg'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '29303'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'US'	System	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Apr 2021 14:43:09
User entered '3'	System	06 Apr 2021 14:04:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
User entered '2'	System	16 Feb 2021 19:00:49
User entered '1'	System	03 Feb 2021 14:39:28

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '03/Feb/2021 09:39'	(b) (4) System	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:57:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'USA-US087-2021-MRNA-1273-P301000017'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Gregory'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Feldman'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '141 Harold Fleming Court'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Spartanburg'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '29303'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'US'	System	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Apr 2021 14:43:09
User entered '3'	System	06 Apr 2021 14:04:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
User entered '2'	System	16 Feb 2021 19:00:49
User entered '1'	System	03 Feb 2021 14:39:28

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered '16/Feb/2021 19:00'	(b) (4) System	16 Feb 2021 19:00:49

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:57:13

**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)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 14:04:20
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 19:00:49

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'USA-US087-2021-MRNA-1273-P301000017'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Gregory'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Feldman'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '141 Harold Fleming Court'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Spartanburg'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '29303'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'US'	System	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Apr 2021 14:43:09
User entered '3'	System	06 Apr 2021 14:04:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
User entered '2'	System	16 Feb 2021 19:00:49
User entered '1'	System	03 Feb 2021 14:39:28

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:47:16
User entered '06/Apr/2021 10:04'	System	06 Apr 2021 14:04:55

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:57:13

**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)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:43:16
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:47:10
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:16
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 14:04:55

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'USA-US087-2021-MRNA-1273-P301000017'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Yes (Y)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'No (N)'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Gregory'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Feldman'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '141 Harold Fleming Court'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'Spartanburg'	System	03 Feb 2021 14:39:08

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:57:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered '29303'	System	03 Feb 2021 14:39:08

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 21:15:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:39:31
User entered 'US'	System	03 Feb 2021 14:39:28

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Apr 2021 14:43:09
User entered '3'	System	06 Apr 2021 14:04:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 20:39:54
	(b) (4)	
User entered '2'	System	16 Feb 2021 19:00:49
User entered '1'	System	03 Feb 2021 14:39:28

**US3302472**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:57:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 01:42:08
User entered '15/Apr/2021 10:43'	System	15 Apr 2021 14:43:09

US3302472

Folder: SAE USA-US087-2021-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:57:13

**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.	Gregory Feldman (b) (4)	29 Apr 2021 12:39:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 01:42:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:43:16
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 14:43:09