

US3622282 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:10:09

All time stamps listed in this document are displayed in GMT

US3622282

Form: Participant Creation

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

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Participant ID

US3622282

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

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US3622282

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3622282

Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 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

US3622282

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3622282

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

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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) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	HIV INFECTION
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

US3622282

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	ASTHMA (SEVERE)
Start date (dd MMM yyyy)	UN UNK 1971
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 1971
Start Year (derived)	1971
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622282

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	POST-TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	PARANOIA
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	NERVE DAMAGE (NEUROPATHY)
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	RIGHT ANKLE SURGERY
Start date (dd MMM yyyy)	3 OCT 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	3 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2020
Start Year (derived)	2020
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	RIGHT ANKLE FRACTURE
Start date (dd MMM yyyy)	UN SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	3 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

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



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	DEEP VEIN THROMBOSIS (SITE UNKNOWN)
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)	
Stop date completely unknown	True
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 (15)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	SCHIZOPHRENIA
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 (17)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	RIGHT ANKLE PAIN
Start date (dd MMM yyyy)	UN SEP 2020
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)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622282

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 09 Apr 2021 19:58:28

Generated On: 10 Jun 2021 09:10:09

Condition	RIGHT ANKLE INFECTION
Start date (dd MMM yyyy)	UN OCT 2020
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)	OCT 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622282

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 08:51
Height (xxx.x)	62 in
Weight (xxx.x)	185 lb
BMI (xxx.x)	33.90769 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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) 28 Jan 2021 15:16:52

Generated On: 10 Jun 2021 09:10:09

Date of assessment (*dd MMM yyyy*) 21 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*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2013

Date of last menstruation unknown False



US3622282

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

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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**

CAR DETAILING

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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) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

<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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

US3622282

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 10 Jun 2021 09:10:09

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

What was the participant's randomization number? 147141

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) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

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) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 08:51
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)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:25
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 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: Physical Examination

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

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) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 OCT 2020

What was the treatment time? (00:00-23:59) 10:52 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 10:52

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) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	09:00 (24 HR)
Collection date and time (derived)	21 OCT 2020 09:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:07	21 OCT 2020 09:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

21 OCT 2020 11:33

PC Open Date & Time

21 OCT 2020 11:12

PC Close Date & Time

21 OCT 2020 13:42

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**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 94.9 °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):

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

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

PC Time Stamp 21 OCT 2020 17:23

PC Open Date & Time 21 OCT 2020 14:37

PC Close Date & Time 22 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**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

101.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 OCT 2020 17:41

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 10:46

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:10:09

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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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 19:24

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 18:58

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 19:08

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:10:09

**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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 19:00

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 11:34

PC Open Date & Time

21 OCT 2020 11:12

PC Close Date & Time

21 OCT 2020 13:42

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 17:25

PC Open Date & Time

21 OCT 2020 14:37

PC Close Date & Time

22 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 17:42

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**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

24 OCT 2020 10:46

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59



US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 19:25

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 18:58

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 19:08

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 19:01

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**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 ☐

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 11:35
PC Open Date & Time	21 OCT 2020 11:12
PC Close Date & Time	21 OCT 2020 13:42

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**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 ☐

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 17:28
PC Open Date & Time	21 OCT 2020 14:37
PC Close Date & Time	22 OCT 2020 11:59



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 17:44
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 10:47
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 19:25
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

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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US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

		Yes <input type="checkbox"/>
PC Time stamp	25 OCT 2020 18:58	
PC Open Date & Time	25 OCT 2020 12:00	
PC Close Date & Time	26 OCT 2020 11:59	



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**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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US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 19:09
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:10:09

**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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US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 19:01
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3622282

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 10 Jun 2021 09:10:09

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3622282

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 10 Jun 2021 09:10:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622282

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Nov 2020 19:18:24

Generated On: 10 Jun 2021 09:10:09

---

Was Contact Attempted? Yes ☒ No ☐

---

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

---

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

---

Comments UNABLE TO CONTACT;  
MESSAGES LEFT

---

*If Contact Not Made, please provide Comments*

---

US3622282

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Nov 2020 19:18:24

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID VISIT2

US3622282

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

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

US3622282

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

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

US3622282

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3622282

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

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

US3622282

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID VISIT3

US3622282

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3622282

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:09

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.*

**US3622282**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

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

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3622282

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:15:27

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 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"/>



**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

---

22 DEC 2020 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2020 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 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"/>



**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 13:36:36

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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	15 FEB 2021 08:48:54
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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	20 FEB 2021 14:13:37
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59



US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 MAR 2021 08:35:35
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	05 MAR 2021 11:36:21
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 <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 MAR 2021 09:42:43
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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

23 MAR 2021 09:22:49

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 19:56:08

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 21:19:45

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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

13 APR 2021 14:46:18

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 09:43:04

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59



US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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

23 APR 2021 08:29:56

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 09:34:28

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 <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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 <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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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°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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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="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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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="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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 467

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59



US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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="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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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°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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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 <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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2022 23:59



US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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



US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	19 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2022 23:59
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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐  
Yes ☐

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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25 OCT 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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06 DEC 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

**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 ☐

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

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[Patient Cloud Close Date & Time](#)

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13 DEC 2022 23:59

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:09

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"/>

**US3622282**

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2022 23:59

US3622282

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:10:09

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:33:32

US3622282

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 18:22:05

Generated On: 10 Jun 2021 09:10:09

---

Was Contact Attempted? Yes ☒ No ☐

---

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

---

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

---

Comments UNABLE TO CONTACT;  
MESSAGES LEFT

---

*If Contact Not Made, please provide Comments*

---



US3622282

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 18:22:05

Generated On: 10 Jun 2021 09:10:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

UNABLE TO CONTACT;  
MESSAGES LEFT

*If Contact Not Made, please provide Comments*

US3622282

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 18:22:05

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 18:22:05

Generated On: 10 Jun 2021 09:10:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622282

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 18:22:05

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 18:22:05

Generated On: 10 Jun 2021 09:10:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622282

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 18:22:05

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

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

Visit date (dd MMM yyyy)	15 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
------------	--------



US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:34 (24 HR)
Vital Signs Date and Time (derived)	15 APR 2021 09:34
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	78 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622282

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

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.*

US3622282

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 APR 2021

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

15 APR 2021 09:50

US3622282

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:07:51

Generated On: 10 Jun 2021 09:10:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3622282**

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

**Form: Continuing**

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

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622282

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:10:09

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

**US3622282**

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

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

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

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3622282

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

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

US3622282

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:19:40

Generated On: 10 Jun 2021 09:10:09

Date of updated informed consent ( <i>dd MMM yyyy</i> )	9 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> )	9 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 type="radio"/> Not Administered <input checked="" 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

US3622282

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3622282

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Height	ND - Not Done
Weight	ND - Not Done
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)	9 FEB 2021
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 12:23
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)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3622282

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Height	ND - Not Done
Weight	ND - Not Done
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)	9 FEB 2021
Time of assessment (00:00-23:59)	14:13 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 14:13
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3622282

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

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3622282

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

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

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) 9 FEB 2021

What was the treatment time? (00:00-23:59) 13:40 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 13:40

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

US3622282

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00-23:59)	13:00 (24 HR)
Collection date and time (derived)	9 FEB 2021 13:00



US3622282

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00 - 23:59)	13:03
Collection Date and Time (derived)	9 FEB 2021 13:03

US3622282

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

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 14:10:57

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:21:47

Generated On: 10 Jun 2021 09:10:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3622282

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:21:47

Generated On: 10 Jun 2021 09:10:09

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

US3622282

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	OLD29

US3622282

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

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)	15 APR 2021
Time of assessment (00:00-23:59)	09:34 (24 HR)
Vital Signs Date and Time (derived)	15 APR 2021 09:34
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3622282

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

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)	15 APR 2021
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	15 APR 2021 10:54
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3622282

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

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.*



US3622282

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

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) 15 APR 2021

What was the treatment time? (00:00-23:59) 10:22 (24 HR)

Treatment Date and Time (derived) 15 APR 2021 10:22

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

US3622282

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 02:25:54

Generated On: 10 Jun 2021 09:10:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3622282**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

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

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*

**US3622282**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

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

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622282

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Jan 2021 15:15:24

Generated On: 10 Jun 2021 09:10:09

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

AEID	USA-US085-2020-MRNA-1273-P30
	1000002
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	26 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	7

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EAB) (1725)

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US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

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

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

---

PARTICIPANT MISSED HER  
VISIT 2 APPOINTMENT TODAY.  
ATTEMPTED TO CONTACT  
MULTIPLE TIMES TODAY.  
CALLED EMERGENCY  
CONTACT AND HE STATED SHE  
WAS IN THE HOSPITAL FOR  
ABOUT 1.5 WEEKS DUE TO  
FOOT/ANKLE SURGERY.  
CONTACT PERSON WITH  
LIMITED KNOWLEDGE OF  
EVENTS.

UPDATE AFTER REVIEWING  
MEDICAL RECORDS:

HX OF RIGHT ANKLE FX  
APPROXIMATELY 3 MONTHS  
AGO, SEPT 2020. S/P R ANKLE  
ORIF 10/3/20. HAS  
NON-HEALING, DRAINING  
SURGICAL SCAR TO R ANKLE.  
MED HX: COPD, DVT, AIDS,  
BIPOLAR DISORDER, COPD,  
DIABETES, SEIZURES, AND A  
SMOKER.

PT. WENT TO ER ON 11/6, WITH  
RLE REDNESS, SWELLING,  
TENDERNESS, AND OPEN  
SURGICAL SCAR. ALSO C/O  
SEVERE PAIN TO R ANKLE X 10  
DAYS PRIOR, AND WAS  
UNABLE TO SLEEP. INITIAL VS:  
B/P- 143/92, P-112, TEMP 99.9  
ORAL. RESP-25, NAD, BUT WITH  
DECREASED AIR MOVEMENT



US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

---

AND WHEEZING. IT WAS ALSO  
NOTED THAT SHE SEEMED  
DISORIENTED AND CONFUSED.  
SISTER PROVIDED ADDITIONAL  
INFO BY PHONE SINCE PPT IS  
POOR HISTORIAN. DX WORKUP  
AND DONE PRIOR TO  
ADMISSION: ABNORMAL LABS  
OF SIGNIFICANCE; ELEVATED  
CRP- 12.3, WBC-12.75, POSITIVE  
UA, ABG 7.39/40/62;  
RADIOLOGY: CXR WITH  
BIBASILAR INTERSTITIAL  
DENSITIES, ANKLE, CT OF  
HEAD, AND US OF BLES. SHE  
WAS GIVEN ZOSYN,  
VANCOMYCIN, NARCAN,  
NEBULIZERS, SUPPLEMENTAL  
O2 VIA NASAL CANNULA, AND  
IV FLUIDS.

ADMITTED BY IM AND SEEN  
BY ORTHO AND ID. BC  
COLLECTED SAME DAY WAS  
POSITIVE FOR E. FAECALIS. IV  
ABX THERAPY AND HIV  
HANDLED BY ID. R ANKLE  
SYMPTOMS IMPROVED AFTER  
BEGINNING ABX THERAPY. BC  
X3 DAYS WERE POSITIVE FROM  
INITIAL DRAW (11/6/20).  
HOWEVER, HER HOSPITAL  
STAY WAS PROLONGED DUE  
PERSISTENT FEVER AND  
WORSENING MENTAL STATUS,  
WITH INCREASED LETHARGY  
AND EPISODES OF AGITATION.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

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ADDITIONAL DIAGNOSTIC  
WORKUP WAS DONE TO RULE  
NEW INFECTIOUS PROCESSES.  
CONTINUOUS BEDSIDE EEG  
WAS ALSO DONE DUE TO HER  
AMS.

DISCHARGE SUMMARY  
UPDATE: ADMITTED FOR  
TREATMENT OF SEPSIS  
SECONDARY TO CELLULITIS  
AND GRAM POSITIVE  
BACTEREMIA, WHICH LATER  
GREW ENTEROCOCCUS  
FAECALIS.

US DVT BLE (11/25/2020):  
NEGATIVE FOR ACUTE DVT IN  
THE BILATERAL LOWER  
EXTREMITIES.

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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)	1

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

AEID	USA-US085-2020-MRNA-1273-P30 1000002
Adverse event	ALTERED MENTAL STATUS (PROLONGATION OF HOSPITALIZATION)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	26 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

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Number of Days in ICU	7
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

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PATIENT WAS ADMITTED TO  
THE HOSPITAL NOVEMBER 6,  
2020 FOR SIGNIFICANT RIGHT  
ANKLE CELLULITIS.

PARTICIPANT'S MEDICAL  
HISTORY INCLUDES COPD,  
BI-POLAR DISORDER,  
SCHIZOPHRENIA, SEIZURES.

AT ADMISSION SHE WAS  
NOTED TO HAVE  
INTERMITTENT CONFUSION  
AND LETHARGY. DURING HER  
HOSPITAL ADMISSION SHE  
HAD A PROGRESSION IN HER  
LETHARGY WITH PERIODS OF  
AGGRESSION. A CT AND AN  
MRI OF THE BRAIN BOTH  
WITHOUT IV CONTRAST

PERFORMED 11/10/2020  
SHOWED NO INTRACRANIAL  
ABNORMALITY: NEGATIVE  
EXAMS. CONTINUOUS VIDEO  
EEG STARTED ON 11/11/2020

SHOWED MILD DIFFUSE  
ENCEPHALOPATHY, BUT NO  
EPILEPTIFORM DISCHARGES  
WERE SEEN, AND NO SEIZURES.

ON 11/16/2020 THERE WAS  
EVIDENCE OF SEVERE DIFFUSE  
ENCEPHALOPATHY; ON

11/17/2020 THERE WAS  
EVIDENCE OF CORTICAL  
DYSFUNCTION. A REPEAT CT  
OF THE BRAIN WAS ALSO

DONE AND WAS STILL  
NEGATIVE FOR INTRACRANIAL  
ABNORMALITIES. A LUMBAR

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

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PUNCTURE PERFORMED  
11/15/2020 WAS NEGATIVE FOR  
MENINGITIS.

NEUROLOGIST THOUGHT THE  
ALTERED MENTAL STATUS  
COULD POSSIBLY BE ACUTE  
METABOLIC  
ENCEPHALOPATHY.

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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)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	ACUTE CYSTITIS WITHOUT HEMATURIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

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



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

AEID	USA-US085-2020-MRNA-1273-P30 1000002
Adverse event	HYPOTENSION (1ST EPISODE)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 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)	6 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	26 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	7

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	A COUPLE RAPID RESPONSES WERE CALLED THROUGHOUT HER STAY FOR FEBRILE EPISODES WITH SIGNIFICANT HYPOTENSION REQUIRING FLUID RESUSCITATION.
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)	1

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	FUNGAL INFECTION (BILATERAL INGUINAL AREAS)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	FUNGAL INFECTION (PANNUS FOLD)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	FISSURE INTERGLUTEAL FOLD
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Form: Adverse Events (7)

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



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	INTERMITTENT WHEEZING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	6 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	LETHARGY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	6 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	HYPOGLYCEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (10)

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

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	ATELECTASIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	6 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

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



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

AEID	USA-US085-2020-MRNA-1273-P30 1000002
Adverse event	HYPOTENSION (2ND EPISODE)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 NOV 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)	6 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	26 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	A COUPLE RAPID RESPONSES WERE CALLED THROUGHOUT HER STAY FOR FEBRILE EPISODES WITH SIGNIFICANT HYPOTENSION REQUIRING FLUID RESUSCITATION.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

AEID

Adverse event

DIFFICULTY SWALLOWING

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)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

AEID

Adverse event

RIGHT ANKLE CELLULITIS

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)

6 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

AEID

Adverse event

EPISODES OF AGITATION

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)

14 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

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



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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

AEID

Adverse event

CHRONIC AVASCULAR  
NECROSIS OF DISTAL FEMUR  
AND PROXIMAL TIBIA

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)

6 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒  
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

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

Is the adverse event serious?

Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐  
No ☐  
Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

AEID	USA-US085-2020-MRNA-1273-P30
	1000002
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 JAN 2021
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)	31 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	DIFFUSE ENCEPHALOPATHY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 NOV 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

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) _____	

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

AEID

Adverse event

EVIDENCE OF BILATERAL  
CORTICAL DYSFUNCTION  
(MAX RIGHT HEMISPHERE)

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)

18 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒  
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

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

Is the adverse event serious?

Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐  
No ☐  
Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

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



US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

AEID	USA-US085-2021-MRNA-1273-P30 1000014
Adverse event	BONE INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

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

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

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PARTICIPANT CALLED AND  
REPORTED SHE WAS  
ADMITTED TO HOSPITAL ON  
25FEB2021 FOR BONE  
INFECTION. SHE REPORTED  
SHE RECEIVED IV  
ANTIBIOTICS. SHE DOES NOT  
KNOW NAMES OR DOSES OF  
ANTIBIOTICS. WILL UPDATE  
ONCE MEDICAL RECORDS ARE  
OBTAINED.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	HYPOCALCEMIA (2ND EPISODE)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	HYPOKALEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	HYPOMAGNESEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	HYPOMAGNESEMIA (2ND EPISODE)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

AEID

Adverse event

HYPOCALCEMIA

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)

06 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy)

09 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

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

Is the adverse event serious?

Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐  
No ☐  
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

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)	_____

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	HYPOCALCEMIA (3RD EPISODE)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 10 Jun 2021 09:10:09

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) _____	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	HYPOKALEMIA (2ND EPISODE)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	ELECTROLYTE IMBALANCE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	CONSTIPATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 09:10:09

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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

AEID	
Adverse event	SEVERE RIGHT ANKLE PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 10 Jun 2021 09:10:09

---

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

Yes ☒

No ☐

---

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

---



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication TRIUMEQ

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 600/50/300

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication LATUDA

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

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 (2)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 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 (3)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DEPAKOTE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY, SCHIZOPHRENIA,  
SEIZURES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 2000
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 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 (4)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication SEROQUEL

Prophylaxis Yes ☐  
No ☒

Indication PARANOIA

Dose per administration 400

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA, CHRONIC  
OBSTRUCTIVE PULMONARY  
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		3 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)		6 NOV 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 (7)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication LYRICA

Prophylaxis Yes ☐  
No ☒

Indication NERVE DAMAGE

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication XARELTO

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR DEEP VEIN  
THROMBOSIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

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

EVERY 4 TO 6 HOURS AS  
NEEDED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 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 (10)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DUONEB (IPRATROPIUM BROMIDE/ALBUTEROL)

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 0.5/3

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS AS NEEDED

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE 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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (12)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication NEOSPORIN (BACITRACIN,  
NEOMYCIN AND POLYMYXIN  
B)

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE INFECTION

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		3 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)		6 NOV 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 (13)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication CEFEPIME

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS/UTI

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

EVERY 12 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS/UTI

Dose per administration 1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	8 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication NARCAN

Prophylaxis Yes ☐  
No ☒

Indication LETHARGY - SUSPECTED  
OPIOID ABUSE

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication KETOROLAC

Prophylaxis Yes ☐  
No ☒

Indication RIGHT LEG PAIN - CELLULITIS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 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 (17)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication INSULIN LISPRO (HUMALOG)

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 1-5

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

If dose unit is Other, specify UNIT

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 EVERY 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 (17)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 (18)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		6 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication IOHEXOL 30000 MG IV  
INJECTION

Prophylaxis Yes ☐  
No ☒

Indication IV CONTRAST (RIGHT LEG CT  
SCAN)

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 (19)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 NOV 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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR  
GASTROINTESTINAL (GI)  
BLEED

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 (20)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	6 NOV 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 NOV 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 (21)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication BUDESONIDE

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA/INTERMITTENT  
WHEEZING

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	25 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN RIGHT ANKLE

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

EVERY 4 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		06 NOV 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 NOV 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 (23)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		6 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 NOV 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) 26 Apr 2021 20:42:43

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Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	8 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 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 (25)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication NICOTINE PATCH

Prophylaxis Yes ☐  
No ☒

Indication SMOKING CESSATION

Dose per administration 21

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 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 NOV 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 (26)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication BLOOD PRESSURE SUPPORT -  
HYPOTENSION

Dose per administration 125

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

PER HOUR CONTINUOUS

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 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) 26 Apr 2021 20:42:43

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Name of Medication PIPERACILLIN/TAZOBACTAM

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS

Dose per administration 3.375

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

EVERY 6 HOURS

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 NOV 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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS

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

EVERY 12 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication IPRATROPIUM  
BROMIDE/ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA - INTERMITTENT  
WHEEZING,  
ATELECTASIS

Dose per administration 2.5/0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Transdermal	<input type="checkbox"/>
	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)	11 NOV 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 NOV 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) 26 Apr 2021 20:42:43

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Name of Medication AMPICILLIN/SULBACTAM

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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) 26 Apr 2021 20:42:43

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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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ABACAVIR

Prophylaxis Yes ☐  
No ☒

Indication HIV

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 (32)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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 (33)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication LAMIVUDINE

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 300

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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 (34)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DOLUTEGRAVIR

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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 (35)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication TRIMETHOPRIM/SULFAMETHO  
XAZOLE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR PCP

Dose per administration 160/800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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 (36)

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Name of Medication AMPICILLIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE  
CELLULITIS/SEPSIS

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

EVERY 4 HOURS

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 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 (37)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication HALDOL

Prophylaxis Yes ☐  
No ☒

Indication EPISODES OF AGITATION

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 (37)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Form: Prior/Concomitant Medication and Vaccination (38)

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Name of Medication MICONAZOLE 2% POWDER

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL INGUINAL AREAS  
AND PANNUS FOLD

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication MEDIHONEY CALCIUM  
ALGINATE DRESSING

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE WOUND CARE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	18 NOV 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 NOV 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)	2	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication TRIAD HYDROPHILIC PASTE

Prophylaxis Yes ☐  
No ☒

Indication INTERGLUTEAL FOLD FISSURE  
WOUND CARE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		18 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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 (41)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication VALPROATE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication SEIZURES

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 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 (41)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		18 NOV 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 NOV 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 (42)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒  
No ☐

Indication DEEP VEIN THROMBOSIS  
PROPHYLAXIS

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

EVERY 12 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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EAB) (1725)

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		18 NOV 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 NOV 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 (43)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPOKALEMIA

Dose per administration 10

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

If dose unit is Other, specify MEQ

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 EVERY 2 HOURS

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) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 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 (44)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication NORMAL SALINE IV

Prophylaxis Yes ☐  
No ☒

Indication HYPOTENSION

Dose per administration 1-2

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

If dose unit is Other, specify LITER

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 AS ORDERED FOR SIGNIFICANT  
HYPOTENSION

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 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 (45)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication LACTATED RINGERS IV

Prophylaxis Yes ☐  
No ☒

Indication HYPOTENSION

Dose per administration 1

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

If dose unit is Other, specify LITER

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 AS ORDERED FOR SIGNIFICANT  
HYPOTENSION

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 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 (46)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication CALCIUM GLUCONATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOCALCEMIA (2ND EPISODE)

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 NOV 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 (47)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOMAGNESEMIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		12 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 NOV 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 (48)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ACYCLOVIR

Prophylaxis Yes ☒  
No ☐

Indication POTENTIAL CNS INFECTION

Dose per administration 550

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

EVERY 8 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 (48)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 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 (49)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication CEFEPIME

Prophylaxis Yes ☒  
No ☐

Indication POTENTIAL CNS INFECTION

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

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 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 (50)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication VANCOMYCIN

Prophylaxis Yes ☒  
No ☐

Indication POTENTIAL CNS INFECTION

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

EVERY 12 HOURS

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	15 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 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 (51)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DEXTROSE 50%

Prophylaxis Yes ☐  
No ☒

Indication HYPOGLYCEMIA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 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 (52)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication ATIVAN

Prophylaxis Yes ☐  
No ☒

Indication EPISODES OF AGITATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 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"/>

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOMAGNESEMIA

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

EVERY 2 HOURS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 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 (54)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE PAIN

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	21 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication AMPICILLIN/SULBACTAM

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 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 (55)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	20 NOV 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 NOV 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 (56)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication POTASSIUM CHLORIDE ER

Prophylaxis Yes ☐  
No ☒

Indication HYPOKALEMIA (3RD EPISODE)

Dose per administration 20

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

If dose unit is Other, specify MEQ

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 EVERY2 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 (56)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	23 NOV 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 NOV 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 (57)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication POTASSIUM SODIUM  
PHOSPHATES (2 PKS)

Prophylaxis Yes ☐  
No ☒

Indication HYPOKALEMIA (3RD EPISODE)

Dose per administration 2

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

If dose unit is Other, specify PACKS

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 THREE TIMES IN 24 HOURS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

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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)		23 NOV 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 NOV 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 (58)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication LIDOCAINE 4% PATCH

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE PAIN

Dose per administration 1

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

If dose unit is Other, specify PATCH

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 (58)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 NOV 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 NOV 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 (59)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 17

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 (59)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 NOV 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 NOV 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 (60)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication SENNA - DOCUSATE

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 8.6/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 NOV 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 NOV 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 (61)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DIVALPROEX DR

Prophylaxis Yes ☐  
No ☒

Indication SEIZURES

Dose per administration 125

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 (61)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 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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Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication NARCAN

Prophylaxis Yes ☐  
No ☒

Indication LETHARGY - SUSPECTED  
OPIOID ABUSE

Dose per administration 0.4

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 (62)

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DIVALPROEX DR

Prophylaxis Yes ☐  
No ☒

Indication SEIZURES

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 (63)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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 (64)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication ELECTROLYTE - A INFUSION

Prophylaxis Yes ☐  
No ☒

Indication ELECTROLYTE IMBALANCE

Dose per administration 125

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 (64)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 NOV 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)

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Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR PUNCTURE

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 (65)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRADERMAL	
Start date (dd MMM yyyy)	15 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Form: Prior/Concomitant Medication and Vaccination (66)

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Name of Medication RIVAROXABAN

Prophylaxis Yes ☒  
No ☐

Indication DVT PROPHYLAXIS

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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Form: Prior/Concomitant Medication and Vaccination (66)

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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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 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 (67)

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Name of Medication DEXTROSE 5%

Prophylaxis Yes ☐  
No ☒

Indication HYPOGLYCEMIA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 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)

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Name of Medication QUETIAPINE

Prophylaxis Yes ☐  
No ☒

Indication PARANOIA

Dose per administration 400

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 (68)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 NOV 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 NOV 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 (69)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOMAGNESEMIA (2ND EPISODE)

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

EVERY 2 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 NOV 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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Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication D5W 0.45 NS

Prophylaxis Yes ☐  
No ☒

Indication UNKNOWN

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

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 (70)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		19 NOV 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 NOV 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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Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTENSION (1ST EPISODE)  
AND HYPOTENSION (2ND  
EPISODE)

Dose per administration 1-2

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

AS ORDERED FOR SIGNIFICANT  
HYPOTENSION

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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	Transdermal	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 NOV 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 NOV 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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Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOMAGNESEMIA (2ND EPISODE)

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

EVERY 2 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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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 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 NOV 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 NOV 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 (73)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DOTAREM

Prophylaxis Yes ☐  
No ☒

Indication MRI RIGHT ANKLE WITH AND WITHOUT CONTRAST

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ABACAVIR

Prophylaxis Yes ☐  
No ☒

Indication HIV

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 (74)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 NOV 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 NOV 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 (75)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication LAMIVUDINE

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 300

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 (75)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 NOV 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 NOV 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 (76)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DOLUTEGRAVIR

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 NOV 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 NOV 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 (77)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES, MUSCLE ACHES,  
JOINT ACHES, CHILLS, FEVER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) 26 Apr 2021 20:42:43

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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)		21 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (78)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication TRIUMEQ

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 600/50/300

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 (78)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (79)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication DEPAKOTE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 (79)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication SEROQUEL

Prophylaxis Yes ☐  
No ☒

Indication PARANOIA

Dose per administration 400

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 (80)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 2000
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11	NOV 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 (81)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication XARELTO

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR DVT

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 (81)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 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 (82)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication BUDESONIDE (PULMICORT)

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication	SUPPLEMENTAL O2 VIA NASAL CANNULA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	UNKNOWN
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	2L
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	CONTINUOUS
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)	06 NOV 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 NOV 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 (84)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐  
No ☒

Indication FEVER

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 (84)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		21 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (85)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 (85)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

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 (86)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ALBUTEROL SULFATE  
(PROAIR)

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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

If dose unit is Other, specify MCG

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 (87)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 2005	
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)		
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 (88)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication ATROVENT

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 17

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

If dose unit is Other, specify MCG

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 (88)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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 2011	
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) _____		
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 (89)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT FOOT PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)		26 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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 (90)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐  
No ☒

Indication FEVER

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 (90)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	21 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)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (91)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

Name of Medication AMOXICILLIN/CLAVULANIC  
ACID

Prophylaxis Yes ☐  
No ☒

Indication RIGHT ANKLE CELLULITIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

	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)	25 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 14 Jan 2021 15:15:26

Generated On: 10 Jun 2021 09:10:09

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Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 22:02:43

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
6 NOV 2020	CHEST X RAY	Diagnostic	
6 NOV 2020	RIGHT FOOT X RAY	Diagnostic	
6 NOV 2020	RIGHT ANKLE X RAY	Diagnostic	
6 NOV 2020	CT TIB-FIB RIGHT WITH IV CONTRAST	Diagnostic	
6 NOV 2020	ELECTROCARDIOGRAM (EKG)	Diagnostic	
6 NOV 2020	ULTRASOUND BILATERAL UPPER EXTREMITIES	Diagnostic	
10 NOV 2020	CT BRAIN WITHOUT IV CONTRAST	Diagnostic	
10 NOV 2020	MRI BRAIN WITHOUT IV CONTRAST	Diagnostic	
11 NOV 2020	MID LINE INSERTION - ULTRASOUND GUIDED	Adverse Event	
11 NOV 2020	CT ABD/PELVIS WITHOUT IV CONTRAST	Diagnostic	
12 NOV 2020	CHEST X RAY	Diagnostic	
11 NOV 2020	PORTABLE EEG	Diagnostic	
11 NOV 2020	BEDSIDE EEG MONITORING CONTINUOUS	Diagnostic	
11 NOV 2020	TRANSTHORACIC ECHO	Diagnostic	
15 NOV 2020	LUMBAR PUNCTURE	Diagnostic	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Data signed: (b) (4) 05 Mar 2021 22:02:43

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 NOV 2020	CHEST X RAY	Diagnostic	
17 NOV 2020	CT BRAIN WITHOUT IV CONTRAST	Diagnostic	
21 NOV 2020	CHEST X RAY	Diagnostic	
22 NOV 2020	CHEST X RAY	Diagnostic	
24 NOV 2020	MRI RIGHT ANKLE WITH AND WITHOUT IV CONTRAST	Diagnostic	
25 NOV 2020	US DVT UPPER BILATERAL EXTREMITIES	Diagnostic	
25 NOV 2020	US DVT LOWER BILATERAL EXTREMITIES	Diagnostic	
06 NOV 2020	BLOOD CULTURE	Diagnostic	
06 NOV 2020	ARTERIAL BLOOD GASES	Diagnostic	
06 NOV 2020	URINALYSIS	Diagnostic	
06 NOV 2020	C-REACTIVE PROTEIN	Diagnostic	
06 NOV 2020	COMPLETE BLOOD COUNT AND DIFFERENTIAL	Diagnostic	
06 NOV 2020	COMPLETE METABOLIC PANEL	Diagnostic	
17 NOV 2020	COMPLETE METABOLIC PANEL	Diagnostic	
12 NOV 2020	MAGNESIUM BLOODWORK	Diagnostic	
16 NOV 2020	MAGNESIUM BLOODWORK	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 14 Jan 2021 15:15:26

Generated On: 10 Jun 2021 09:10:09

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Date of dosing discontinuation (dd MMM yyyy)	8 DEC 2020
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---

Primary reason for dosing discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Due to SARS-COV-2 <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

UNABLE TO COMPLY WITH  
PROTOCOL VISIT  
REQUIREMENTS FOR SECOND  
VACCINATION

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:09

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 ☐

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/NOV/2020 18:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	09/DEC/2020 13:03
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

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	10/DEC/2020 17:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	05/JAN/2021 11:46
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

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	27/JAN/2021 13:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/FEB/2021 15:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	24/FEB/2021 10:38
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

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	01/MAR/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

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/MAR/2021 12:33
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

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Data signed: (b) (4) 26 Apr 2021 20:42:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	21/APR/2021 13:34
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

US3622282

Folder: SAE USA-US085-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 22:02:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2021-MRNA-1273-P301000014
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3622282

Folder: SAE USA-US085-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 22:02:43

Generated On: 10 Jun 2021 09:10:09

SAEID	USA-US085-2021-MRNA-1273-P301000014
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	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	01/MAR/2021 15:19
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

US3622282 (Prod: University of Miami)

**US3622282**

**Form: Participant Creation**

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

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:26:53
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'US3622282'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:29



**US3622282**

**Folder: Screening**

**Form: Visit Date**

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

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:05
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 14:59:29

US3622282

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:05
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:30

US3622282

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:05
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	21 Oct 2020 14:59:29

**US3622282**

**Folder: Screening**

**Form: Visit Date**

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

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered 'SCRN'	System	21 Oct 2020 14:59:29

US3622282

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:31

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '51'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'YEARS'	System	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '51'	System	21 Oct 2020 14:59:51



**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Female (F)'	Junlin Long (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Junlin Long (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'I'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53



**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53

**US3622282**

**Folder: Screening**

**Form: Demographics**

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

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:12
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:06:53

US3622282

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:17
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 14:59:51

**US3622282**

**Folder: Screening**

**Form: Enrollment**

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

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Oct 2020'	System	21 Oct 2020 14:59:51

**US3622282**

**Folder: Screening**

**Form: Enrollment**

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

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2020'	System	21 Oct 2020 14:59:51

**US3622282**

**Folder: Screening**

**Form: Enrollment**

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

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:17
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Amendment 4 (4)'	Junlin Long (b) (4)	21 Oct 2020 14:59:51

**US3622282**

**Folder: Screening**

**Form: Enrollment**

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

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:17
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 14:59:51



**US3622282**

**Folder: Screening**

**Form: Enrollment**

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

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:17
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 14:59:51

**US3622282**

**Folder: Screening**

**Form: Enrollment**

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

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:17
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 14:59:51
	(b) (4)	

**US3622282**

**Folder: Screening**

**Form: Enrollment**

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

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:17
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 14:59:51

US3622282

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:27:17
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:30

US3622282

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'I'	System	21 Oct 2020 14:59:56

**US3622282**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

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

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:10:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:07:09

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Oct 2020 17:08:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:08:44
Data point term sent to Coder	System	21 Oct 2020 17:07:50
User entered 'hiv infection'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:07:33



US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 13:03:47
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 1997'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:07:33

**US3622282**

**Folder: Screening**

**Form: Medical History (1)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:07:33

**US3622282**

**Folder: Screening**

**Form: Medical History (1)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:07:33

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:15:59
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:07:33

**US3622282**

**Folder: Screening**

**Form: Medical History (1)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:07:33

**US3622282**

**Folder: Screening**

**Form: Medical History (1)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 1997'	System	21 Oct 2020 17:07:33

**US3622282**

**Folder: Screening**

**Form: Medical History (1)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '1997'	System	21 Oct 2020 17:07:33

**US3622282**

**Folder: Screening**

**Form: Medical History (1)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:07:33



**US3622282**

**Folder: Screening**

**Form: Medical History (1)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:07:33

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 22:34:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:34:37
Data point term sent to Coder	System	21 Oct 2020 17:08:51
User entered 'asthma (severe)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 1971'	Junlin Long	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 1971'	System	21 Oct 2020 17:08:37



**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '1971'	System	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:08:37

**US3622282**

**Folder: Screening**

**Form: Medical History (2)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:08:37

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	(b) (4) Coders Import (b) (4) (b) (4)	21 Oct 2020 17:10:33
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4) (b) (4)	21 Oct 2020 17:10:33
Data point term sent to Coders	System	21 Oct 2020 17:09:52
User entered 'bipolar disorder'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 1985'	Junlin Long	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:09:03



**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 1985'	System	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '1985'	System	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:09:03

**US3622282**

**Folder: Screening**

**Form: Medical History (3)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:09:03

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:10:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:10:33
Data point term sent to Coder	System	21 Oct 2020 17:09:53
User entered 'anxiety'	Junlin Long (b) (4)	21 Oct 2020 17:09:52

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 1985'	Junlin Long	21 Oct 2020 17:09:52

**US3622282**

**Folder: Screening**

**Form: Medical History (4)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:09:52



**US3622282**

**Folder: Screening**

**Form: Medical History (4)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:09:52

**US3622282**

**Folder: Screening**

**Form: Medical History (4)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:09:52

**US3622282**

**Folder: Screening**

**Form: Medical History (4)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:09:52

**US3622282**

**Folder: Screening**

**Form: Medical History (4)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 1985'	System	21 Oct 2020 17:09:52

**US3622282**

**Folder: Screening**

**Form: Medical History (4)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '1985'	System	21 Oct 2020 17:09:52

**US3622282**

**Folder: Screening**

**Form: Medical History (4)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:09:52

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:10:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:09:52

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	(b) (4) Coders Import (b) (4) (b) (4)	21 Oct 2020 17:11:45
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	21 Oct 2020 17:11:45
Data point term sent to Coders System	System	21 Oct 2020 17:10:55
User entered 'Post-traumatic stress disorder'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:10:25



**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 1985'	Junlin Long	21 Oct 2020 17:10:25

**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:10:25

**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:10:25

**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:10:25

**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:10:25

**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 1985'	System	21 Oct 2020 17:10:25

**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '1985'	System	21 Oct 2020 17:10:25

**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:10:25



**US3622282**

**Folder: Screening**

**Form: Medical History (5)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:10:25

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as SOC: Psychiatric disorders, HLG: Personality disorders and disturbances in behaviour, HLT: Behaviour and socialisation disturbances, PT: Paranoia, LLT: Paranoia - version MedDRA\23.0.	(b) (4) Coders Import (b) (4)	21 Oct 2020 17:11:46
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4)	21 Oct 2020 17:11:46
Data point term sent to Coders	System	21 Oct 2020 17:10:55
User entered 'paranoia'	Junlin Long (b) (4)	21 Oct 2020 17:10:40
	(b) (4)	

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 1985'	Junlin Long	21 Oct 2020 17:10:40

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:10:40

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:10:40

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:10:40

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:10:40

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 1985'	System	21 Oct 2020 17:10:40



**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '1985'	System	21 Oct 2020 17:10:40

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:10:40

**US3622282**

**Folder: Screening**

**Form: Medical History (6)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:10:40

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Nerve injuries NEC, PT: Nerve injury, LLT: Nerve damage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:39:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:39:10
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
Data point term sent to Coder	System	21 Oct 2020 17:11:57
User entered 'nerve damage (neuropathy)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2001'	Junlin Long	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:11:17



**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 2001'	System	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2001'	System	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:11:17

**US3622282**

**Folder: Screening**

**Form: Medical History (7)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	21 Oct 2020 17:11:17

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:52:10
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'mh updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 13:26:09
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:29:59
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle operation, LLT: Ankle operation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:12:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:12:36
Data point term sent to Coder	System	21 Oct 2020 17:12:00
User entered 'right ankle surgery'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '3 Oct 2020'	Junlin Long	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:11:49



**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '3 Oct 2020'	Junlin Long	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Oct 2020'	System	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2020'	System	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Oct 2020'	System	21 Oct 2020 17:11:49

**US3622282**

**Folder: Screening**

**Form: Medical History (8)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2020'	System	21 Oct 2020 17:11:49

US3622282

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\23.0.	(b) (4) Coders Import (b) (4) (b) (4)	09 Dec 2020 19:59:56
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4) (b) (4)	09 Dec 2020 19:59:56
Data point term sent to Coders	System	09 Dec 2020 19:59:14
User entered 'diabetes'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:59:02



US3622282

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:10:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	09 Dec 2020 19:59:02

**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'I'	Junlin Long	09 Dec 2020 19:59:02

**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'Yes (Y)'	Junlin Long	09 Dec 2020 19:59:02

**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	09 Dec 2020 19:59:02

**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	09 Dec 2020 19:59:02

**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:02

**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:02

**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:02



**US3622282**

**Folder: Screening**

**Form: Medical History (9)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:02

US3622282

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizures - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Dec 2020 20:01:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:01:00
Data point term sent to Coder	System	09 Dec 2020 20:00:15
User entered 'seizures'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'I'	Junlin Long	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'Yes (Y)'	Junlin Long	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:21



**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:21

**US3622282**

**Folder: Screening**

**Form: Medical History (10)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	09 Dec 2020 19:59:21

US3622282

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 13:27:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 13:27:12
Data point term sent to Coder	System	26 Jan 2021 13:26:23
User entered 'right ankle fracture'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'un Sep 2020'	Junlin Long	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'No (N)'	Junlin Long	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '3 Oct 2020' reason for change: New Information	Junlin Long (b) (4)	26 Jan 2021 13:25:54
User entered 'un Oct 2020'	Junlin Long (b) (4)	26 Jan 2021 13:25:37



**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Sep 2020'	System	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2020'	System	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Oct 2020'	System	26 Jan 2021 13:25:37

**US3622282**

**Folder: Screening**

**Form: Medical History (11)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2020'	System	26 Jan 2021 13:25:37

US3622282

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 13:29:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 13:29:09
Data point term sent to Coder	System	26 Jan 2021 13:28:25
User entered 'post menopause'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'un UNK 2013'	Junlin Long	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 13:28:18



**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 2013'	System	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2013'	System	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 13:28:18

**US3622282**

**Folder: Screening**

**Form: Medical History (12)**

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

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 13:28:18

US3622282

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User coded data point as SOC: Social circumstances, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	(b) (4)	26 Jan 2021 15:07:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 15:07:07
Data point term sent to Coder	System	26 Jan 2021 15:06:35
User entered 'smoker'	Junlin Long (b) (4)	26 Jan 2021 15:05:48
	(b) (4)	



**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	26 Jan 2021 15:05:48

**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

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

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'I'	Junlin Long	26 Jan 2021 15:05:48

**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

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

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 15:05:48

**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

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

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	26 Jan 2021 15:05:48

**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 15:05:48

**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:05:48

**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:05:48

**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:05:48



**US3622282**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:05:48

US3622282

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 11:08:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	02 Mar 2021 11:08:42
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:16:37
Query 'Per MM, please expand the abbreviation ' answered with 'Abbreviation has been expanded.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:35:10
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	25 Feb 2021 12:34:51 25 Feb 2021 12:34:50
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 12:34:50
User entered 'Deep Vein Thrombosis (SITE UNKNOWN)' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 12:34:50
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 14:53:07
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: DVT - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 21:09:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 21:09:28
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	28 Jan 2021 15:16:52
Data point term sent to Coder	System	26 Jan 2021 15:19:54
User entered 'dvt (site unknown)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:19:06

US3622282

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:10:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'un UNK 2019'	Junlin Long	26 Jan 2021 15:19:06

**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 15:19:06

**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'No (N)'	Junlin Long	26 Jan 2021 15:19:06

**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	26 Jan 2021 15:19:06

**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'I'	Junlin Long	26 Jan 2021 15:19:06

**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 2019'	System	26 Jan 2021 15:19:06



**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2019'	System	26 Jan 2021 15:19:06

**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:06

**US3622282**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:06

US3622282

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
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.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 09:33:52
' (Site from DM).		
User closed query 'Per MM, please expand the abbreviation.	(b) (4), (b) (6)	26 Feb 2021 09:17:44
' (Site from DM).		
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.	(b) (4), (b) (6)	25 Feb 2021 14:18:00
' answered with 'Con Med has been updated reflecting participant is taking Montelukast for COPD since year 2000. Hospital medical records reflect participant is taking Montelukast for COPD as well.' (Site from DM).		
Query 'Per MM, please expand the abbreviation.	(b) (4), (b) (6)	25 Feb 2021 12:43:45
' answered with 'Abbreviation expanded' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:37:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 12:37:51
Data point term sent to Coder	System	25 Feb 2021 12:36:52
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 12:36:24
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 12:36:24
User entered 'Chronic Obstructive Pulmonary Disease' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 12:36:24

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Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
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)	18 Feb 2021 19:25:55
User opened query 'Per MM, please expand the abbreviation. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 14:52:29
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
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 - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 15:20:14
Data point term sent to Coder	(b) (4)	
User entered 'copd'	System	26 Jan 2021 15:19:53
	Junlin Long (b) (4)	26 Jan 2021 15:19:20
	(b) (4)	

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	26 Jan 2021 15:19:20

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'I'	Junlin Long	26 Jan 2021 15:19:20

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 15:19:20



**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long	26 Jan 2021 15:19:20

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 15:19:20

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:20

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:20

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:20

**US3622282**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:20

US3622282

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:10:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
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)	26 Feb 2021 09:34:10
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'ConMed updated. Participant has been on treatment for Schizophrenia since year 2000.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:31:21
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)	18 Feb 2021 19:24:40
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizophrenia NEC, PT: Schizophrenia, LLT: Schizophrenia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Jan 2021 15:20:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:20:14
Data point term sent to Coder	System	26 Jan 2021 15:19:54
User entered 'schizophrenia'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:19:49

US3622282

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:31:27
User entered 'UN UNK 2000' reason for change: New Information	(b) (4), (b) (6)	25 Feb 2021 12:31:27
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:19:49



US3622282

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:31:27
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 12:31:27
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:19:49

**US3622282**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 15:19:49

**US3622282**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:10:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 15:19:49

**US3622282**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '0'	Junlin Long	26 Jan 2021 15:19:49

**US3622282**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Jan 2000'	System	25 Feb 2021 12:31:27
User entered empty.	System	26 Jan 2021 15:19:49

**US3622282**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2000'	System	25 Feb 2021 12:31:27
User entered empty.	System	26 Jan 2021 15:19:49

**US3622282**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:49

**US3622282**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	26 Jan 2021 15:19:49



US3622282

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain ankle - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Feb 2021 12:19:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:19:09
Data point term sent to Coder	System	25 Feb 2021 12:17:48
User entered 'Right Ankle Pain'	(b) (4), (b) (6)	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'UN Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Sep 2020'	System	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2020'	System	25 Feb 2021 12:17:22



**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	25 Feb 2021 12:17:22

**US3622282**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	25 Feb 2021 12:17:22

US3622282

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:10:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:58:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Infection, LLT: Infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 06:30:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:30:41
Data point term sent to Coder	System	07 Apr 2021 16:04:49
User entered 'right ankle infection'	(b) (4), (b) (6)	07 Apr 2021 16:04:36

US3622282

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:10:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:58:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	07 Apr 2021 16:04:47
User entered 'UN Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:04:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 16:04:36
User entered '00 Oct 2020' (non-conformant).	(b) (4), (b) (6)	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:58:28
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:58:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:58:28
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:58:28
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:04:36



**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered 'Oct 2020'	System	07 Apr 2021 16:04:47
User entered empty.	System	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered '2020'	System	07 Apr 2021 16:04:47
User entered empty.	System	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User entered empty.	System	07 Apr 2021 16:04:36

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:12:58

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 17:12:58

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '08:51'	Junlin Long	21 Oct 2020 17:12:58

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered '21 Oct 2020 08:51'	System	21 Oct 2020 17:12:58



US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '62' in	Junlin Long	21 Oct 2020 17:12:58
DataPoint set to visible.	System	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '185' lb	Junlin Long	21 Oct 2020 17:12:58
DataPoint set to visible.	System	21 Oct 2020 14:59:56

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered '33.90769'	System	21 Oct 2020 17:12:58
DataPoint set to visible.	System	21 Oct 2020 14:59:56

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered 'kg/m2'	System	21 Oct 2020 17:12:58
DataPoint set to visible.	System	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Other (Other)'	Junlin Long	21 Oct 2020 17:12:58

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:12:58

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:12:58



**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered 'bpm'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered 'breaths/min'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:12:58

**US3622282**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered 'mmHg'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User entered 'mmHg'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44



US3622282

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44

**US3622282**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:10:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:13:08

**US3622282**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:10:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 17:13:08

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:10:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 17:13:55

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:10:09

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:13:55

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:10:09

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:50:52
Query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 13:27:40
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 13:27:27
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 13:27:27
User opened query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:43:59
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
User entered 'Surgically sterile (SURGICALLY STERILE)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:13:55

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:10:09

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:13:55

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:10:09

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
Signature has been broken.	Junlin Long	26 Jan 2021 13:27:27
User entered empty; reason for change Per Query Resolution	Junlin Long	26 Jan 2021 13:27:27
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2013'	Junlin Long	21 Oct 2020 17:13:55



**US3622282**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:10:09**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:13:55

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:10:09

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 13:27:27
User entered 'un UNK 2013' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 13:27:27
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:10:09

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:13:55

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31



US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'car detailing'	Junlin Long	21 Oct 2020 17:14:31



US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

**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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

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)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'I'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:14:31

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:44
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:14:31



US3622282

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 15:00:10

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 15:00:10

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Clinic (Clinic)'	Junlin Long	21 Oct 2020 15:00:10

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'VISIT1'	System	21 Oct 2020 15:00:10

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:09

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:32

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:09

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '147141'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:32

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:09

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:32

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:09

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:14:54



US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:09

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:54

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:10:09**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:54

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:10:09**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:54

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:09

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:14:54

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:09

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
Signature has been broken.	(b) (4) Junlin Long (b) (4)	28 Oct 2020 16:13:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Junlin Long (b) (4)	28 Oct 2020 16:13:08
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4)	21 Oct 2020 17:14:54
DataPoint set to visible.	(b) (4) System	21 Oct 2020 14:59:51

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:15:49



US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 17:15:49

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '08:51'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered '21 Oct 2020 08:51'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '97.9' F	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (Oral)'	Junlin Long	21 Oct 2020 17:15:49



**US3622282**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '103'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'bpm'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '16'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'breaths/min'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '123'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '68'	Junlin Long	21 Oct 2020 17:15:49



US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered missing code ND - Not Done.	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 17:15:49

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '11:25'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered '21 Oct 2020 11:25'	System	21 Oct 2020 17:15:49



US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '98.8' F	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (Oral)'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '103'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'bpm'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '20'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'breaths/min'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '121'	Junlin Long	21 Oct 2020 17:15:49



US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '67'	Junlin Long	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:15:52

US3622282

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:15:52

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 15:00:28



US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '10:52'	Junlin Long	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered '21 Oct 2020 10:52'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Left Arm (LEFT ARM)'	Junlin Long	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'ONCE'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:16:05



US3622282

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:16:05

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '09:00'	Junlin Long	21 Oct 2020 17:16:05

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered '21 Oct 2020 09:00'	System	21 Oct 2020 17:16:05

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:10:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '21 Oct 2020'	Junlin Long	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4)	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:16:31

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '09:07'	Junlin Long	21 Oct 2020 17:16:31

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered '21 Oct 2020 09:07'	System	21 Oct 2020 17:16:31



US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4)	21 Oct 2020 17:16:31

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:16:31

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered empty.	System	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:16:35

**US3622282**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'I'	System	21 Oct 2020 17:16:35

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:19', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b' User entered 'Yes (Y)'	System	21 Oct 2020 15:33:55
	System	21 Oct 2020 15:33:55



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b' User entered '98.8'	System	21 Oct 2020 15:33:55
	System	21 Oct 2020 15:33:55

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b' User entered 'No (N)'	System	21 Oct 2020 15:33:55
	System	21 Oct 2020 15:33:55

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b' User entered '21 Oct 2020 11:33'	System	21 Oct 2020 15:33:55
	System	21 Oct 2020 15:33:55

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 13:42'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:21:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1' User entered 'Yes (Y)'	System	21 Oct 2020 21:23:41
	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:22:40', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1' User entered '94.9'	System	21 Oct 2020 21:23:41
	System	21 Oct 2020 21:23:41



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:22:49', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	System	21 Oct 2020 21:23:41
User entered 'Yes (Y)'	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
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 'please refer to conmed line 77.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 08:18:23
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).	Junlin Long (b) (4)	16 Feb 2021 14:34:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:23:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	(b) (4)	
User entered '1'	System	21 Oct 2020 21:23:41
	System	21 Oct 2020 21:23:41
	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:23:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1' User entered '0'	System	21 Oct 2020 21:23:41
	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:23:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1' User entered '21 Oct 2020 17:23'	System	21 Oct 2020 21:23:41
	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 14:37'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 2'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:41:01', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0' User entered 'Yes (Y)'	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:15', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0' User entered '101.0'	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:30', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0' User entered 'Yes (Y)'	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
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 'please refer to conmed line 77.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 08:26:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Junlin Long (b) (4)	16 Feb 2021 14:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0'	(b) (4)	
User entered '1'	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0' User entered '0'	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:10:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:41:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0' User entered '22 Oct 2020 17:41'	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 3'	System	21 Oct 2020 15:00:28



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:45:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6' User entered 'Yes (Y)'	System	24 Oct 2020 15:24:51
	System	24 Oct 2020 15:24:51

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:45:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6' User entered '97.3'	System	24 Oct 2020 15:24:51
	System	24 Oct 2020 15:24:51

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:45:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6' User entered 'No (N)'	System	24 Oct 2020 15:24:51
	System	24 Oct 2020 15:24:51

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6' User entered '24 Oct 2020 10:46'	System	24 Oct 2020 15:24:51
	System	24 Oct 2020 15:24:51

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:10:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 4'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:36', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d' User entered 'Yes (Y)'	System	24 Oct 2020 23:24:59
	System	24 Oct 2020 23:24:59



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d' User entered '98.0'	System	24 Oct 2020 23:24:59
	System	24 Oct 2020 23:24:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d' User entered 'No (N)'	System	24 Oct 2020 23:24:59
	System	24 Oct 2020 23:24:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:10:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d' User entered '24 Oct 2020 19:24'	System	24 Oct 2020 23:24:59
	System	24 Oct 2020 23:24:59

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 5'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:57:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11' User entered 'Yes (Y)'	System	25 Oct 2020 22:58:06
	System	25 Oct 2020 22:58:06

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:57:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11' User entered '98.0'	System	25 Oct 2020 22:58:06
	System	25 Oct 2020 22:58:06



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:57:56', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11'	System	25 Oct 2020 22:58:06
User entered 'No (N)'	System	25 Oct 2020 22:58:06

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:03', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11' User entered '25 Oct 2020 18:58'	System	25 Oct 2020 22:58:06
	System	25 Oct 2020 22:58:06

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:10:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 6'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9' User entered 'Yes (Y)'	System	26 Oct 2020 23:08:29
	System	26 Oct 2020 23:08:29

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9' User entered '99.2'	System	26 Oct 2020 23:08:29
	System	26 Oct 2020 23:08:29

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:16', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9' User entered 'No (N)'	System	26 Oct 2020 23:08:29
	System	26 Oct 2020 23:08:29



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9' User entered '26 Oct 2020 19:08'	System	26 Oct 2020 23:08:29
	System	26 Oct 2020 23:08:29

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 7'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f' User entered 'Yes (Y)'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:44', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f' User entered '99.0'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:48', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f' User entered 'No (N)'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f' User entered '27 Oct 2020 19:00'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56



US3622282

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:10:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:23', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6'	System	21 Oct 2020 15:34:58
User entered 'None (1)'	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:35', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6' User entered 'No (N)'	System	21 Oct 2020 15:34:58
	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6' User entered 'No (N)'	System	21 Oct 2020 15:34:58
	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:45', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6' User entered 'None (1)'	System	21 Oct 2020 15:34:58
	System	21 Oct 2020 15:34:58

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6' User entered '21 Oct 2020 11:34'	System	21 Oct 2020 15:34:58
	System	21 Oct 2020 15:34:58



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 13:42'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered 'None (1)'	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3' User entered 'No (N)'	System	21 Oct 2020 21:25:07
	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:17', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3' User entered 'No (N)'	System	21 Oct 2020 21:25:07
	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:22', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered 'None (1)'	System	21 Oct 2020 21:25:07

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:25:02', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered '21 Oct 2020 17:25'	System	21 Oct 2020 21:25:07



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 14:37'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 2'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:37', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:42', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered 'No (N)'	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:46', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96' User entered 'No (N)'	System	22 Oct 2020 21:43:02
	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered 'None (1)'	System	22 Oct 2020 21:43:02

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:58', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96' User entered '22 Oct 2020 17:42'	System	22 Oct 2020 21:43:02
	System	22 Oct 2020 21:43:02



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 3'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'None (1)'	System	24 Oct 2020 15:25:44
	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:35', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'No (N)'	System	24 Oct 2020 15:25:44
	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'No (N)'	System	24 Oct 2020 15:25:44
	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:42', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'None (1)'	System	24 Oct 2020 15:25:44
	System	24 Oct 2020 15:25:44

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:59', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered '24 Oct 2020 10:46'	System	24 Oct 2020 15:25:44
	System	24 Oct 2020 15:25:44



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 4'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:02', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a' User entered 'None (1)'	System	24 Oct 2020 23:25:23
	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:07', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a' User entered 'No (N)'	System	24 Oct 2020 23:25:23
	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:11', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a' User entered 'No (N)'	System	24 Oct 2020 23:25:23
	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:15', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a' User entered 'None (1)'	System	24 Oct 2020 23:25:23
	System	24 Oct 2020 23:25:23

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:20', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a' User entered '24 Oct 2020 19:25'	System	24 Oct 2020 23:25:23
	System	24 Oct 2020 23:25:23



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 5'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'None (1)'	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:17', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'No (N)'	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:21', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'No (N)'	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'None (1)'	System	25 Oct 2020 22:58:31

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc' User entered '25 Oct 2020 18:58'	System	25 Oct 2020 22:58:31
	System	25 Oct 2020 22:58:31



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 6'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2'	System	26 Oct 2020 23:08:55
User entered 'None (1)'	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2' User entered 'No (N)'	System	26 Oct 2020 23:08:55
	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:41', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2' User entered 'No (N)'	System	26 Oct 2020 23:08:55
	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:46', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2'	System	26 Oct 2020 23:08:55
User entered 'None (1)'	System	26 Oct 2020 23:08:55

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2' User entered '26 Oct 2020 19:08'	System	26 Oct 2020 23:08:55
	System	26 Oct 2020 23:08:55



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 7'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:01', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered 'None (1)'	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:04', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered 'No (N)'	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:07', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17' User entered 'No (N)'	System	27 Oct 2020 23:01:16
	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered 'None (1)'	System	27 Oct 2020 23:01:16

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17' User entered '27 Oct 2020 19:01'	System	27 Oct 2020 23:01:16
	System	27 Oct 2020 23:01:16



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:02', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:06', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:10:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:15', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:19', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:26', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'No (N)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:10:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered '21 Oct 2020 11:35'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 13:42'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:25:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d' User entered 'None (0)'	System	21 Oct 2020 21:28:48
	System	21 Oct 2020 21:28:48



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Some interference with activity (2)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Some interference with activity (2)'	System	21 Oct 2020 21:28:48

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:27', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d' User entered 'None (0)'	System	21 Oct 2020 21:28:48
	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:28:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Some interference with activity not requiring medical attention (2)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:28:12', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d' User entered 'No (N)'	System	21 Oct 2020 21:28:48
	System	21 Oct 2020 21:28:48

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:28:44', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d' User entered '21 Oct 2020 17:28'	System	21 Oct 2020 21:28:48
	System	21 Oct 2020 21:28:48

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '21 Oct 2020 14:37'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:00:28



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 2'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered 'None (0)'	System	22 Oct 2020 21:44:13
	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:22', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered 'None (0)'	System	22 Oct 2020 21:44:13
	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec'	System	22 Oct 2020 21:44:13
User entered 'No interference with activity (1)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec'	System	22 Oct 2020 21:44:13
User entered 'No interference with activity (1)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:42', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered 'None (0)'	System	22 Oct 2020 21:44:13
	System	22 Oct 2020 21:44:13

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:55', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec'	System	22 Oct 2020 21:44:13
User entered 'No interference with activity (1)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:44:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered 'No (N)'	System	22 Oct 2020 21:44:13
	System	22 Oct 2020 21:44:13



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:44:11', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered '22 Oct 2020 17:44'	System	22 Oct 2020 21:44:13
	System	22 Oct 2020 21:44:13

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 3'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered 'None (0)'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:09', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered 'None (0)'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:11', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered 'None (0)'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:14', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered 'None (0)'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:16', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered 'None (0)'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered 'None (0)'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:22', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered 'No (N)'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813' User entered '24 Oct 2020 10:47'	System	24 Oct 2020 15:26:10
	System	24 Oct 2020 15:26:10

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 4'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:25', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:10:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:37', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:44', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'No (N)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:50', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered '24 Oct 2020 19:25'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:00:28



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 5'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered 'None (0)'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:36', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered 'None (0)'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered 'None (0)'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:41', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered 'None (0)'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered 'None (0)'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:45', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered 'None (0)'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:49', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered 'No (N)'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered '25 Oct 2020 18:58'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 6'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:08', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33



US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:17', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:19', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'No (N)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:29', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered '26 Oct 2020 19:09'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:10:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 7'	System	21 Oct 2020 15:00:28



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:20', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:10:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:23', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32' User entered 'None (0)'	System	27 Oct 2020 23:01:41
	System	27 Oct 2020 23:01:41

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:26', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32' User entered 'None (0)'	System	27 Oct 2020 23:01:41
	System	27 Oct 2020 23:01:41

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32' User entered 'None (0)'	System	27 Oct 2020 23:01:41
	System	27 Oct 2020 23:01:41

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:10:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:35', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'No (N)'	System	27 Oct 2020 23:01:41

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32' User entered '27 Oct 2020 19:01'	System	27 Oct 2020 23:01:41
	System	27 Oct 2020 23:01:41



**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:10:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:12:42
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

**US3622282**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered 'Yes (Y)'	Junlin Long	28 Oct 2020 16:13:51

**US3622282**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered '28 Oct 2020'	Junlin Long	28 Oct 2020 16:13:51

**US3622282**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	28 Oct 2020 16:13:51

**US3622282**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered empty.	Junlin Long (b) (4)	28 Oct 2020 16:13:51

US3622282

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered 'Yes (Y)'	Junlin Long	28 Oct 2020 16:13:54

**US3622282**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'I'	System	28 Oct 2020 16:13:54



**US3622282**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered 'Yes (Y)'	Junlin Long	04 Nov 2020 16:38:33

**US3622282**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered '4 Nov 2020'	Junlin Long	04 Nov 2020 16:38:33

**US3622282**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	04 Nov 2020 16:38:33

**US3622282**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered empty.	Junlin Long	04 Nov 2020 16:38:33

US3622282

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Nov 2020 16:38:37

**US3622282**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:35:15
User entered 'I'	System	04 Nov 2020 16:38:37

**US3622282**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:57
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
User entered 'Yes (Y)'	Junlin Long	12 Nov 2020 17:13:09

**US3622282**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:57
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
User entered '12 Nov 2020'	Junlin Long (b) (4)	12 Nov 2020 17:13:09



US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:57
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
User entered 'Contact Not Made (CONTACT NOT MADE)'	Junlin Long (b) (4)	12 Nov 2020 17:13:09

US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:57
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
User entered 'unable to contact; messages left'	Junlin Long (b) (4)	12 Nov 2020 17:13:09

US3622282

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:57
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
User entered 'Yes (Y)'	Junlin Long	12 Nov 2020 17:13:12

**US3622282**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:57
User entered 'I'	System	12 Nov 2020 17:13:12

US3622282

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	09 Dec 2020 13:47:10

**US3622282**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	09 Dec 2020 13:47:10

US3622282

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 13:47:10

**US3622282**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User entered 'VISIT2'	System	09 Dec 2020 13:47:10



US3622282

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Yes (Y)'	Junlin Long	09 Dec 2020 13:47:17

**US3622282**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User entered 'I'	System	09 Dec 2020 13:47:17

**US3622282**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 12:23:51

**US3622282**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 12:23:51

**US3622282**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 12:23:51

**US3622282**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 12:23:51

US3622282

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Yes (Y)'	Junlin Long	04 Jan 2021 12:23:56

**US3622282**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User entered 'I'	System	04 Jan 2021 12:23:56



**US3622282**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 12:24:02

**US3622282**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 12:24:02

**US3622282**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 12:24:02

US3622282

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 12:24:02

US3622282

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Yes (Y)'	Junlin Long	04 Jan 2021 12:24:07

**US3622282**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User entered 'I'	System	04 Jan 2021 12:24:07

**US3622282**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 12:24:12

**US3622282**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 12:24:12



**US3622282**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 12:24:12

**US3622282**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 12:24:12

**US3622282**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Yes (Y)'	Junlin Long	04 Jan 2021 12:24:18

**US3622282**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User entered 'I'	System	04 Jan 2021 12:24:18

**US3622282**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 12:24:25

**US3622282**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 12:24:25

**US3622282**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 12:24:25

**US3622282**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User entered 'VISIT3'	System	04 Jan 2021 12:24:25



US3622282

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Yes (Y)'	Junlin Long	04 Jan 2021 12:24:31

**US3622282**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:06:41
User entered '1'	System	04 Jan 2021 12:24:31

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-02-09T13:36:17', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1cc44ae1-d4f4-468e-9559-0c21317f984b'	System	09 Feb 2021 18:36:41
User entered 'No (N)'	System	09 Feb 2021 18:36:41

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-02-09T13:36:26', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1cc44ae1-d4f4-468e-9559-0c21317f984b'	System	09 Feb 2021 18:36:41
User entered 'No (N)'	System	09 Feb 2021 18:36:41

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-02-09T13:36:36', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1cc44ae1-d4f4-468e-9559-0c21317f984b' User entered '09 Feb 2021 13:36:36'	System	09 Feb 2021 18:36:41

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-02-15T08:48:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '71fbb3a0-9904-4503-94fc-bc1b173d0b9b'	System	15 Feb 2021 13:49:02
User entered 'No (N)'	System	15 Feb 2021 13:49:02

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-02-15T08:48:33', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '71fbb3a0-9904-4503-94fc-bc1b173d0b9b'	System	15 Feb 2021 13:49:02
User entered 'No (N)'	System	15 Feb 2021 13:49:02



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-02-15T08:48:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '71fbb3a0-9904-4503-94fc-bc1b173d0b9b'	System	15 Feb 2021 13:49:02
User entered '15 Feb 2021 08:48:54'	System	15 Feb 2021 13:49:02

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-02-20T14:13:33', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee305f03-8dad-4261-8b84-97a9b2a33ca7'	System	20 Feb 2021 19:13:42
User entered 'No (N)'	System	20 Feb 2021 19:13:42

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-02-20T14:13:29', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee305f03-8dad-4261-8b84-97a9b2a33ca7'	System	20 Feb 2021 19:13:42
User entered 'No (N)'	System	20 Feb 2021 19:13:42

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-02-20T14:13:37', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee305f03-8dad-4261-8b84-97a9b2a33ca7'	System	20 Feb 2021 19:13:42
User entered '20 Feb 2021 14:13:37'	System	20 Feb 2021 19:13:42

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-01T08:35:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6770c8d9-1255-4a7c-bd4f-bf853cc52e10'	System	01 Mar 2021 13:35:39
User entered 'Yes (Y)'	System	01 Mar 2021 13:35:39

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-03-01T08:34:21', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6770c8d9-1255-4a7c-bd4f-bf853cc52e10'	System	01 Mar 2021 13:35:39
User entered 'No (N)'	System	01 Mar 2021 13:35:39

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-01T08:34:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6770c8d9-1255-4a7c-bd4f-bf853cc52e10'	System	01 Mar 2021 13:35:39
User entered 'No (N)'	System	01 Mar 2021 13:35:39

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-01T08:35:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6770c8d9-1255-4a7c-bd4f-bf853cc52e10'	System	01 Mar 2021 13:35:39
User entered 'No (N)'	System	01 Mar 2021 13:35:39

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-03-01T08:35:35', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6770c8d9-1255-4a7c-bd4f-bf853cc52e10'	System	01 Mar 2021 13:35:39
User entered '01 Mar 2021 08:35:35'	System	01 Mar 2021 13:35:39

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-05T11:34:51', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '5b706254-e339-4d66-ac95-b37a34a908a4'	System	05 Mar 2021 16:36:33
User entered 'Yes (Y)'	System	05 Mar 2021 16:36:33

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-03-05T11:34:59', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '5b706254-e339-4d66-ac95-b37a34a908a4'	System	05 Mar 2021 16:36:33
User entered 'No (N)'	System	05 Mar 2021 16:36:33

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-05T11:35:07', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '5b706254-e339-4d66-ac95-b37a34a908a4'	System	05 Mar 2021 16:36:33
User entered 'No (N)'	System	05 Mar 2021 16:36:33

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-05T11:35:30', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '5b706254-e339-4d66-ac95-b37a34a908a4'	System	05 Mar 2021 16:36:33
User entered 'Yes (Y)'	System	05 Mar 2021 16:36:33

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Please 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 (64bf4b8fbe868f1a)', Time: '2021-03-05T11:36:11', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '5b706254-e339-4d66-ac95-b37a34a908a4'	System	05 Mar 2021 16:36:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Mar 2021 16:36:33

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-03-05T11:36:21', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '5b706254-e339-4d66-ac95-b37a34a908a4'	System	05 Mar 2021 16:36:33
User entered '05 Mar 2021 11:36:21'	System	05 Mar 2021 16:36:33



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-16T09:42:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e145bcaa-fe5c-4025-9293-4dd59bed9f21'	System	16 Mar 2021 13:42:48
User entered 'No (N)'	System	16 Mar 2021 13:42:48

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-03-16T09:42:30', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e145bcaa-fe5c-4025-9293-4dd59bed9f21'	System	16 Mar 2021 13:42:48
User entered 'No (N)'	System	16 Mar 2021 13:42:48

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-03-16T09:42:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e145bcaa-fe5c-4025-9293-4dd59bed9f21'	System	16 Mar 2021 13:42:48
User entered '16 Mar 2021 09:42:43'	System	16 Mar 2021 13:42:48

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-23T09:22:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '521eedf1-a588-4272-aff8-b72f2ba77961'	System	23 Mar 2021 13:22:54
User entered 'No (N)'	System	23 Mar 2021 13:22:54

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-03-23T09:22:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '521eedf1-a588-4272-aff8-b72f2ba77961'	System	23 Mar 2021 13:22:54
User entered 'No (N)'	System	23 Mar 2021 13:22:54

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-03-23T09:22:49', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '521eedf1-a588-4272-aff8-b72f2ba77961'	System	23 Mar 2021 13:22:54
User entered '23 Mar 2021 09:22:49'	System	23 Mar 2021 13:22:54

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-03-26T19:56:02', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'df957a33-7c21-41a9-ac67-53eec8a4856c'	System	26 Mar 2021 23:56:12
User entered 'No (N)'	System	26 Mar 2021 23:56:12



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-03-26T19:56:04', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'df957a33-7c21-41a9-ac67-53eec8a4856c'	System	26 Mar 2021 23:56:12
User entered 'No (N)'	System	26 Mar 2021 23:56:12

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-03-26T19:56:08', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'df957a33-7c21-41a9-ac67-53eec8a4856c'	System	26 Mar 2021 23:56:12
User entered '26 Mar 2021 19:56:08'	System	26 Mar 2021 23:56:12

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-04-03T21:19:25', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ecdc288a-fa75-4951-85a6-c47f571146f0'	System	04 Apr 2021 01:21:37
User entered 'No (N)'	System	04 Apr 2021 01:21:37

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-04-03T21:19:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ecdc288a-fa75-4951-85a6-c47f571146f0'	System	04 Apr 2021 01:21:37
User entered 'No (N)'	System	04 Apr 2021 01:21:37

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-04-03T21:19:45', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ecdc288a-fa75-4951-85a6-c47f571146f0'	System	04 Apr 2021 01:21:37
User entered '03 Apr 2021 21:19:45'	System	04 Apr 2021 01:21:37



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-04-13T14:46:06', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '64fe087e-bdd7-4a1b-8ff7-8f6f2b010723'	System	13 Apr 2021 18:46:22
User entered 'No (N)'	System	13 Apr 2021 18:46:22

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-04-13T14:46:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '64fe087e-bdd7-4a1b-8ff7-8f6f2b010723'	System	13 Apr 2021 18:46:22
User entered 'No (N)'	System	13 Apr 2021 18:46:22

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-04-13T14:46:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '64fe087e-bdd7-4a1b-8ff7-8f6f2b010723'	System	13 Apr 2021 18:46:22
User entered '13 Apr 2021 14:46:18'	System	13 Apr 2021 18:46:22

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-04-16T09:42:51', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '8aae4d5e-efc2-4fb6-98dc-eb6e5acee274'	System	16 Apr 2021 13:43:09
User entered 'No (N)'	System	16 Apr 2021 13:43:09

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-04-16T09:42:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '8aae4d5e-efc2-4fb6-98dc-eb6e5acee274'	System	16 Apr 2021 13:43:09
User entered 'No (N)'	System	16 Apr 2021 13:43:09

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-04-16T09:43:04', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '8aae4d5e-efc2-4fb6-98dc-eb6e5acee274'	System	16 Apr 2021 13:43:09
User entered '16 Apr 2021 09:43:04'	System	16 Apr 2021 13:43:09

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-04-23T08:29:49', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2fbc27c3-012d-4a6d-bb38-a5fe98fbdadb'	System	25 Apr 2021 14:55:43
User entered 'No (N)'	System	25 Apr 2021 14:55:43



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-04-23T08:29:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2fbc27c3-012d-4a6d-bb38-a5fe98fbdadb'	System	25 Apr 2021 14:55:43
User entered 'No (N)'	System	25 Apr 2021 14:55:43

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-04-23T08:29:56', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2fbc27c3-012d-4a6d-bb38-a5fe98fbdbdb' User entered '23 Apr 2021 08:29:56'	System	25 Apr 2021 14:55:43

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[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 (64bf4b8fbe868f1a)', Time: '2021-04-30T09:34:16', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e2107b7e-a7c6-4cdc-8ca9-d56bcfbd42f4'	System	30 Apr 2021 13:34:37
User entered 'No (N)'	System	30 Apr 2021 13:34:37

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

Have you been exposed to someone with 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 (64bf4b8fbe868f1a)', Time: '2021-04-30T09:34:19', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e2107b7e-a7c6-4cdc-8ca9-d56bcfbd42f4'	System	30 Apr 2021 13:34:37
User entered 'No (N)'	System	30 Apr 2021 13:34:37

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-04-30T09:34:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e2107b7e-a7c6-4cdc-8ca9-d56bcfbd42f4'	System	30 Apr 2021 13:34:37
User entered '30 Apr 2021 09:34:28'	System	30 Apr 2021 13:34:37



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:19:05



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:19:05



**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:19:05

**US3622282**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:10:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:10:09**

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 19:32:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-03-01T08:33:16', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee395db0-65a5-4ad7-bfb6-1fba5024d458'	System	01 Mar 2021 13:33:37
User entered 'No (N)'	System	01 Mar 2021 13:33:37

US3622282

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:10:09

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:32:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64bf4b8fbe868f1a)', Time: '2021-03-01T08:33:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee395db0-65a5-4ad7-bfb6-1fba5024d458'	System	01 Mar 2021 13:33:37
User entered '01 Mar 2021 08:33:32'	System	01 Mar 2021 13:33:37

**US3622282**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long	01 Feb 2021 16:11:11

US3622282

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
Signature has been broken.	Junlin Long	31 Mar 2021 13:34:28
User entered '16 Dec 2020' reason for change: Data Entry Error	Junlin Long	31 Mar 2021 13:34:28
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '13 Jan 2021'	Junlin Long	01 Feb 2021 16:11:11



US3622282

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
Signature has been broken.	Junlin Long	31 Mar 2021 13:34:28
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Junlin Long	31 Mar 2021 13:34:28
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	01 Feb 2021 16:11:11

US3622282

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	31 Mar 2021 13:34:28
User entered 'unable to contact; messages left'	(b) (4)	
reason for change: Data Entry Error	Junlin Long (b) (4)	31 Mar 2021 13:34:28
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'unable to talk with participant; talked	(b) (4)	
with participant's emergency contact.'	Junlin Long (b) (4)	01 Feb 2021 16:11:11
	(b) (4)	

US3622282

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long	01 Feb 2021 16:11:15

**US3622282**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
User entered 'I'	System	01 Feb 2021 16:11:15

**US3622282**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Yes (Y)'	Junlin Long	31 Mar 2021 13:35:20

**US3622282**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered '19 Jan 2021'	Junlin Long	31 Mar 2021 13:35:20

**US3622282**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Contact Not Made (CONTACT NOT MADE)'	Junlin Long (b) (4)	31 Mar 2021 13:35:20

**US3622282**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'unable to contact; messages left'	Junlin Long (b) (4)	31 Mar 2021 13:35:20



US3622282

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Yes (Y)'	Junlin Long (b) (4)	31 Mar 2021 13:35:36

**US3622282**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User entered 'I'	System	31 Mar 2021 13:35:36

**US3622282**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Yes (Y)'	Junlin Long	31 Mar 2021 13:36:06

**US3622282**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered '17 Feb 2021'	Junlin Long (b) (4)	31 Mar 2021 13:36:06

**US3622282**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	31 Mar 2021 13:36:06

**US3622282**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered empty.	Junlin Long (b) (4)	31 Mar 2021 13:36:06

US3622282

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Yes (Y)'	Junlin Long	31 Mar 2021 13:36:13

**US3622282**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User entered 'I'	System	31 Mar 2021 13:36:13



**US3622282**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Yes (Y)'	Junlin Long	31 Mar 2021 13:36:30

**US3622282**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered '19 Mar 2021'	Junlin Long	31 Mar 2021 13:36:30

**US3622282**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	31 Mar 2021 13:36:30

**US3622282**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered empty.	Junlin Long (b) (4)	31 Mar 2021 13:36:30

US3622282

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:22:05
User entered 'Yes (Y)'	Junlin Long	31 Mar 2021 13:36:39

**US3622282**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:41:01
User entered 'I'	System	31 Mar 2021 13:36:39

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Apr 2021 14:09:01
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '15 Apr 2021'	Junlin Long (b) (4)	15 Apr 2021 14:09:01
	(b) (4)	



US3622282

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	15 Apr 2021 14:09:01
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	15 Apr 2021 14:09:01

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '15 Apr 2021'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '09:34'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 09:34'	System	15 Apr 2021 14:09:27

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '97.8' F	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	



**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '78'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 14:09:27

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '20'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 14:09:27

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '124'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 14:09:27

US3622282

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '75'	Junlin Long (b) (4)	15 Apr 2021 14:09:27
	(b) (4)	



**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 14:09:27

US3622282

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	15 Apr 2021 14:09:32
	(b) (4)	

US3622282

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	15 Apr 2021 14:09:32
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Apr 2021 14:09:43
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '15 Apr 2021'	Junlin Long (b) (4)	15 Apr 2021 14:09:43
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered '09:50'	Junlin Long (b) (4)	15 Apr 2021 14:09:43
	(b) (4)	

**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 09:50'	System	15 Apr 2021 14:09:43

US3622282

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Apr 2021 14:09:46
	(b) (4)	



**US3622282**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 14:09:46

**US3622282**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Apr 2021 22:07:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:35:53

**US3622282**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Apr 2021 22:07:51
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:35:53

**US3622282**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Apr 2021 22:07:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:35:53

**US3622282**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Apr 2021 22:07:51
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:35:53

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long	09 Feb 2021 18:16:50

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long	09 Feb 2021 18:16:50

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	09 Feb 2021 18:16:50



**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 18:16:50

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:10:09

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long	09 Feb 2021 18:17:10

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:10:09**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:19:40
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:38:27

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:10:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long	09 Feb 2021 18:17:10

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:10:09**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:19:40
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:38:27

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:10:09

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long	09 Feb 2021 18:17:10

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:10:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	09 Feb 2021 18:17:10

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:10:09**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	09 Feb 2021 18:17:10



**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:10:09**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Not Administered (NA)'	Junlin Long (b) (4)	09 Feb 2021 18:17:10

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:10:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Feb 2021 18:17:10

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:10:09**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered '1'	System	09 Feb 2021 18:17:10

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'I'	System	09 Feb 2021 18:17:10

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:10:09**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:10:09**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered empty.	System	10 Feb 2021 11:36:48
DataPoint set to visible.	System	09 Feb 2021 18:17:10

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	10 Feb 2021 11:36:48



**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:10:09**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered empty.	System	10 Feb 2021 11:36:48
DataPoint set to visible.	System	09 Feb 2021 18:17:10

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '12:23'	Junlin Long	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered '9 Feb 2021 12:23'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '98.2' F	Junlin Long (b) (4)	10 Feb 2021 11:36:48



US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Oral (Oral)'	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered empty.	Junlin Long (b) (4)	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '95'	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'bpm'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '16'	Junlin Long (b) (4)	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'breaths/min'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '100'	Junlin Long	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'mmHg'	System	10 Feb 2021 11:36:48



**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '69'	Junlin Long	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'mmHg'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:10:09**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered empty.	System	10 Feb 2021 11:36:48
DataPoint set to visible.	System	09 Feb 2021 18:17:10

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long (b) (4)	10 Feb 2021 11:36:48



**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '14:13'	Junlin Long	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered '9 Feb 2021 14:13'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '98.1' F	Junlin Long (b) (4)	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Oral (Oral)'	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered empty.	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '90'	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'bpm'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '18'	Junlin Long (b) (4)	10 Feb 2021 11:36:48



US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'breaths/min'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '100'	Junlin Long (b) (4)	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'mmHg'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '73'	Junlin Long	10 Feb 2021 11:36:48

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'mmHg'	System	10 Feb 2021 11:36:48

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Feb 2021 11:36:56

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:10:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long (b) (4)	10 Feb 2021 11:36:56

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:02:57



US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:02:57

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

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 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:02:57

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'mRNA-1273'	System	09 Feb 2021 19:02:57
DataPoint set to visible.	System	09 Feb 2021 18:17:10

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:02:57

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '13:40'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:02:57

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered '9 Feb 2021 13:40'	System	09 Feb 2021 19:02:57

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:02:57

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'ONCE'	System	09 Feb 2021 19:02:57



**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 19:02:57

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Feb 2021 11:37:14

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long (b) (4)	10 Feb 2021 11:37:14

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '13:00'	Junlin Long	10 Feb 2021 11:37:14

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:10:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered '9 Feb 2021 13:00'	System	10 Feb 2021 11:37:14

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:10:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Feb 2021 11:37:22

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:10:09**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '9 Feb 2021'	Junlin Long	10 Feb 2021 11:37:22

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:10:09**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered '13:03'	Junlin Long (b) (4)	10 Feb 2021 11:37:22



**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:10:09**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered '9 Feb 2021 13:03'	System	10 Feb 2021 11:37:22

US3622282

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:10:57
User entered 'Yes (Y)'	Junlin Long	10 Feb 2021 11:37:24

**US3622282**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:15:02
User entered '1'	System	10 Feb 2021 11:37:24

**US3622282**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:19:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:21:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:00:18

**US3622282**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:19:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:21:47
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:00:18

**US3622282**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:19:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:21:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:00:18

**US3622282**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:10:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:19:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:21:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:00:18

**US3622282**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:19:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:21:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:00:30



**US3622282**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:19:35
User entered 'I'	System	17 Feb 2021 15:00:30

**US3622282**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:19:35
User entered '1'	System	17 Feb 2021 15:00:30
DataPoint set to visible.	System	17 Feb 2021 15:00:30

**US3622282**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:24:54

US3622282

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 07:42:49
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'Date confirmed; the participant was hospitalized' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:28
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	15 Apr 2021 15:24:54
User entered '15 Apr 2021'	(b) (4), (b) (6)	15 Apr 2021 15:24:54

**US3622282**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:24:54

**US3622282**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:10:09**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	15 Apr 2021 15:24:54

US3622282

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33



**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '09:34'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 09:34'	System	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '78'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 15:26:33



**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '20'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '124'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '75'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:26:33

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 15:26:33

US3622282

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17



**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '10:54'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 10:54'	System	15 Apr 2021 15:27:17

US3622282

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '73'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 15:27:17



**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '20'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '123'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '69'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 15:27:17

**US3622282**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:10:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:24

**US3622282**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:10:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:24



**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:53

**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:53

US3622282

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:53

**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	15 Apr 2021 15:27:53
DataPoint set to visible.	System	17 Feb 2021 15:00:30

**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:53

**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered '10:22'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:53

**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 10:22'	System	15 Apr 2021 15:27:53

US3622282

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:27:53



**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Apr 2021 15:27:53

**US3622282**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:10:09**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Apr 2021 15:27:53

**US3622282**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:25:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:28:00

**US3622282**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:10:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 15:28:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:10:09**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:26
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:47:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:20:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:09:41
User entered 'USA-US085-2020-mRNA-1273-P301000002'	System	19 Nov 2020 18:57:40
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 18:57:40

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'For coding purposes, please split RIGHT ANKLE CELLULITIS/SEPSIS into separate entries' (Site from Coder).	(b) (4), (b) (6)	14 Mar 2021 16:52:10
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 12:09:54
Query 'For coding purposes, please split RIGHT ANKLE CELLULITIS/SEPSIS into separate entries' answered with 'information updated' (Site from Coder).	Junlin Long (b) (4)	04 Jan 2021 15:11:42
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 15:07:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 15:07:28
Data point term sent to Coder	System	04 Jan 2021 15:06:21
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:06:18
Coding entries removed.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 15:06:18
User entered 'SEPSIS' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 15:06:18
User opened query 'For coding purposes, please split RIGHT ANKLE CELLULITIS/SEPSIS into separate entries' (Site from Coder).	(b) (4), (b) (6)	26 Dec 2020 20:50:53
User closed query "For coding purposes, FOOT/ANKLE SURGERY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure." canceled ' (Site from Coder).	(b) (4), (b) (6)	26 Dec 2020 20:48:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 19:09:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 19:09:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:09:16
Data point term sent to Coder	System	08 Dec 2020 18:21:27
User entered 'RIGHT ANKLE CELLULITIS/SEPSIS' reason for change: Per Query Resolution	Junlin Long (b) (4)	08 Dec 2020 18:21:04
Query 'For coding purposes, FOOT/ANKLE SURGERY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' canceled ' answered with 'updated' (Site from Coder).	Junlin Long (b) (4)	08 Dec 2020 18:19:33
Data point term sent to Coder	System	08 Dec 2020 18:19:24
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'updated' (Site from Safety).	Junlin Long (b) (4)	08 Dec 2020 18:19:17
Coding entries removed.	Junlin Long (b) (4)	08 Dec 2020 18:19:05
User entered 'hospitalization for right ankle cellulitis/SEPSIS' reason for change: Per Query Resolution	Junlin Long (b) (4)	08 Dec 2020 18:19:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 15:58:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 15:58:57
Data point term sent to Coder	System	08 Dec 2020 15:57:44
Coding entries removed.	(b) (4), (b) (6)	08 Dec 2020 15:57:43
User entered 'Sepsis' reason for change: New Information	(b) (4), (b) (6)	08 Dec 2020 15:57:43
User opened query 'For coding purposes, FOOT/ANKLE SURGERY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' canceled ' (Site from Coder).	(b) (4), (b) (6)	28 Nov 2020 18:07:10



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Foot operation, LLT: Foot surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:14:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:14:06
Data point term sent to Coder	System	24 Nov 2020 18:43:57
Query 'For coding purposes, FOOT/ANKLE SURGERY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:43:55
User opened query 'For coding purposes, FOOT/ANKLE SURGERY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4) (b) (4)	22 Nov 2020 22:24:00
Query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	22 Nov 2020 21:42:01
User opened query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:58:52
Data point term sent to Coder	System	18 Nov 2020 17:29:28
User entered 'Foot/Ankle Surgery'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '06 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	08 Dec 2020 15:57:43
User entered '05 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 17:30:01
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	18 Nov 2020 17:30:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 17:29:08
User entered '00:00'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:30:01
User entered '05 Nov 2020 00:00'	System	18 Nov 2020 17:29:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:15:43
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:15:43
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08



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Form: Adverse Events (1)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:40:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date provided' (Site from Safety).	Junlin Long (b) (4)	04 Jan 2021 15:16:00
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:15:43
User entered '26 Nov 2020' reason for change: Per Query Resolution	Junlin Long (b) (4)	04 Jan 2021 15:15:43
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:20
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:29:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	04 Jan 2021 15:15:43
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 by data change (Site from System).		04 Jan 2021 15:15:43
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
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	18 Nov 2020 17:29:08
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:29:08



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '06 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	08 Dec 2020 15:57:43
User entered '05 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:41:00
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'discharge date provided' (Site from Safety).	Junlin Long (b) (4)	04 Jan 2021 15:16:12
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 15:15:43
User entered '26 Nov 2020' reason for change: Per Query Resolution	Junlin Long (b) (4)	04 Jan 2021 15:15:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:46:06
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:15:43
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:15:43
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Dec 2020 15:57:43
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		08 Dec 2020 15:57:43
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Dec 2020 15:57:43
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Nov 2020 17:29:08
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:15:43
User entered '7' reason for change: New Information	(b) (4)	04 Jan 2021 15:15:43
DataPoint Verified.	Junlin Long (b) (4)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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**Folder: Adverse Events**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:58:46
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:45:59
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:53:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Dec 2020 18:23:05
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Nov 2020 17:29:08
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '1' reason for change: Data Entry Error	Junlin Long (b) (4)	08 Dec 2020 18:23:05
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:29:08

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc ecrf to include a therapeutic procedure' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:18:13
	(b) (4), (b) (6)	21 Apr 2021 19:44:33
Query 'Per DM CLR-RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc ecrf to include a therapeutic procedure' answered with 'Mid-line procedure was done for this AE. Procedure is recorded in Concomitant Procedures. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:26:06
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 12:23:58
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 12:07:27
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 12:07:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Per DM CLR-RQ: Response noted. However, please tick this field if therapeutic surgery/procedure is given. Either update this field or update Con Proc ecrf to include a therapeutic procedure' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:10:18
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:28:20

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'The concomitant procedure that was used to diagnose this AE was added. No Medical treatment procedure or not diagnostic procedure was done for this AE.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 14:50:07
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 02:14:37
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:15:43
User entered '1' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 15:15:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:41:11
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'outcome updated' (Site from Safety).	Junlin Long (b) (4)	04 Jan 2021 15:16:45
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:15:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Junlin Long (b) (4)	04 Jan 2021 15:15:43
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:03
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08



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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, DM CLR RQ: Response noted; however per narrative "PT. WENT TO ER ON 11/6... ALSO C/O SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR". Please review SEVERE PAIN TO R ANKLE needs to be recorded as a separate AE, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:57:42
User closed query 'Per DM CLR - RQ: Site's response noted. However, SUPPLEMENTAL O2 VIA NASAL CANNULA is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:25:39
Query 'Per CDM, DM CLR RQ: Response noted; however per narrative "PT. WENT TO ER ON 11/6... ALSO C/O SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR". Please review SEVERE PAIN TO R ANKLE needs to be recorded as a separate AE, else clarify. ' answered with 'New AE of severe right ankle pain 10 days prior was added.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:31:31
Query 'Per DM CLR - RQ: Site's response noted. However, SUPPLEMENTAL O2 VIA NASAL CANNULA is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Supplemental O2 via Nasal Cannula has been added to ConMed.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:21:46
User opened query 'Per CDM, DM CLR RQ: Response noted; however per narrative "PT. WENT TO ER ON 11/6... ALSO C/O SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR". Please review SEVERE PAIN TO R ANKLE needs to be recorded as a separate AE, else clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:18:32
User closed query 'Per DM CLR: Narrative = SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:18:32

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Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = UNABLE TO SLEEP. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:06:19
Query 'Per DM CLR: Narrative = SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Medical history of right ankle pain with a start date of Sept 2020 was added. No exact date was added as participant does not recall exact date of when the pain started.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:21:14
Query 'Per DM CLR: Narrative = UNABLE TO SLEEP. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'After review, this should not be reported as an AE.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:14:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Per DM CLR - RQ: Site's response noted. However, SUPPLEMENTAL O2 VIA NASAL CANNULA is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:09:35
User opened query 'Per DM CLR: Narrative = UNABLE TO SLEEP. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:08:54
User opened query 'Per DM CLR: Narrative = SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:08:49

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Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = BC X3 DAYS WERE POSITIVE FROM INITIAL DRAW (11/6/20). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.  ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:28:25
User closed query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:20:21
User closed query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:20:19
User closed query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:20:15
Query 'Per DM CLR: Narrative = BC X3 DAYS WERE POSITIVE FROM INITIAL DRAW (11/6/20). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'BC was added in conProc eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:26:39
Query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' answered with 'Concomitant Procedures were added in eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:25:51
Query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' answered with 'Concomitant Procedures were added in eCRF' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:25:40
Query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' answered with 'Concomitant Procedures were added in eCRF' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:25:30

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = BC X3 DAYS WERE POSITIVE FROM INITIAL DRAW (11/6/20). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.  ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 02:14:28
User opened query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:00:32
User closed query 'Per DM CLR: Narrative = BC WERE NEGATIVE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:00:32
User opened query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:00:27
User closed query 'Per DM CLR: Narrative = ELEVATED CRP, POSITIVE UA, ABG 7.39/40/62. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:00:27
User opened query 'Per CDM Re-Query: These procedures were not found in the Concomitant Procedures CRF. Please update or clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:57:19
User closed query 'Per DM CLR: Narrative = SUPPLEMENTAL O2 VIA NASAL CANNULA AND IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:57:19
Query 'Per DM CLR: Narrative = BC WERE NEGATIVE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'BC were positive on 11/6/2020. Correction was made and eCRF updated.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 16:14:51

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Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SUPPLEMENTAL O2 VIA NASAL CANNULA AND IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Supplemental O2 via Nasal Cannula and IV fluids were reviewed and captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 16:13:37
Query 'Per DM CLR: Narrative = ELEVATED CRP, POSITIVE UA, ABG 7.39/40/62. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Labs were performed and captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 16:12:41

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT MISSED HER VISIT 2 APPOINTMENT TODAY. ATTEMPTED TO CONTACT MULTIPLE TIMES TODAY. CALLED EMERGENCY CONTACT AND HE STATED SHE WAS IN THE HOSPITAL FOR ABOUT 1.5 WEEKS DUE TO FOOT/ANKLE SURGERY. CONTACT PERSON WITH LIMITED KNOWLEDGE OF EVENTS.  UPDATE AFTER REVIEWING MEDICAL RECORDS:<br  HX OF RIGHT ANKLE FX APPROXIMATELY 3 MONTHS AGO, SEPT 2020. S/P R ANKLE ORIF 10/3/20. HAS NON-HEALING, DRAINING SURGICAL SCAR TO R ANKLE. MED HX: COPD, DVT, AIDS, BIPOLAR DISORDER, COPD, DIABETES, SEIZURES, AND A SMOKER.  PT. WENT TO ER ON 11/6, WITH RLE REDNESS, SWELLING, TENDERNESS, AND OPEN SURGICAL SCAR. ALSO C/O SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR, AND WAS UNABLE TO SLEEP. INITIAL VS: B/P- 143/92, P-112, TEMP 99.9 ORAL. RESP-25, NAD, BUT WITH DECREASED AIR MOVEMENT AND WHEEZING. IT WAS ALSO NOTED THAT SHE SEEMED DISORIENTED AND CONFUSED. SISTER PROVIDED ADDITIONAL INFO BY PHONE SINCE PPT IS POOR HISTORIAN. DX WORKUP AND DONE PRIOR TO ADMISSION: ABNORMAL LABS OF SIGNIFICANCE; ELEVATED CRP- 12.3, WBC-12.75, POSITIVE UA, ABG 7.39/40/62; RADIOLOGY: CXR WITH BIBASILAR INTERSTITIAL DENSITIES, ANKLE, CT OF HEAD, AND US OF BLES. SHE WAS GIVEN ZOSYN, VANCOMYCIN, NARCAN, NEBULIZERS, SUPPLEMENTAL O2 VIA NASAL CANNULA, AND IV FLUIDS. <br  ADMITTED BY IM AND SEEN BY ORTHO AND ID. BC COLLECTED SAME DAY WAS POSITIVE FOR E. FAECALIS. IV ABX THERAPY AND HIV HANDLED BY ID. R ANKLE SYMPTOMS IMPROVED AFTER BEGINNING	(b) (4), (b) (6)	23 Feb 2021 15:54:26

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
ABX THERAPY. BC X3 DAYS WERE POSITIVE FROM INITIAL DRAW (11/6/20). HOWEVER, HER HOSPITAL STAY WAS PROLONGED DUE PERSISTENT FEVER AND WORSENING MENTAL STATUS, WITH INCREASED LETHARGY AND EPISODES OF AGITATION. ADDITIONAL DIAGNOSTIC WORKUP WAS DONE TO RULE NEW INFECTIOUS PROCESSES. CONTINUOUS BEDSIDE EEG WAS ALSO DONE DUE TO HER AMS.  DISCHARGE SUMMARY UPDATE: ADMITTED FOR TREATMENT OF SEPSIS SECONDARY TO CELLULITIS AND GRAM POSITIVE BACTEREMIA, WHICH LATER GREW ENTEROCOCCUS FAECALIS.  US DVT BLE (11/25/2020): NEGATIVE FOR ACUTE DVT IN THE BILATERAL LOWER EXTREMITIES.' reason for change: Per Query Resolution		
User opened query 'Per DM CLR: Narrative = BC WERE NEGATIVE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:54:10
User opened query 'Per DM CLR: Narrative = SUPPLEMENTAL O2 VIA NASAL CANNULA AND IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:54:02
User opened query 'Per DM CLR: Narrative = ELEVATED CRP, POSITIVE UA, ABG 7.39/40/62. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:53:55
User closed query ' PV Query: "GI bleed" was listed as the indication for pantoprazole. Please confirm if GI bleed was experienced and should be added as an AE/SAE or consider updating the indication (ie. GI bleed prophylaxis).' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 18:00:19

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[Narrative](#)

Audit	User	Time (GMT)
User closed query '(1) PV Query: Please add medical history, DVT, COPD, smoke and schizophrenia, mentioned in narrative to subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 18:00:02
User closed query 'PV Query: Please provide any ankle imaging and results of BLE US.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 17:59:55



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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT MISSED HER VISIT 2 APPOINTMENT TODAY. ATTEMPTED TO CONTACT MULTIPLE TIMES TODAY. CALLED EMERGENCY CONTACT AND HE STATED SHE WAS IN THE HOSPITAL FOR ABOUT 1.5 WEEKS DUE TO FOOT/ANKLE SURGERY. CONTACT PERSON WITH LIMITED KNOWLEDGE OF EVENTS.  UPDATE AFTER REVIEWING MEDICAL RECORDS:<br  HX OF RIGHT ANKLE FX APPROXIMATELY 3 MONTHS AGO, SEPT 2020. S/P R ANKLE ORIF 10/3/20. HAS NON-HEALING, DRAINING SURGICAL SCAR TO R ANKLE. MED HX: COPD, DVT, AIDS, BIPOLAR DISORDER, COPD, DIABETES, SEIZURES, AND A SMOKER.  PT. WENT TO ER ON 11/6, WITH RLE REDNESS, SWELLING, TENDERNESS, AND OPEN SURGICAL SCAR. ALSO C/O SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR, AND WAS UNABLE TO SLEEP. INITIAL VS: B/P- 143/92, P-112, TEMP 99.9 ORAL. RESP-25, NAD, BUT WITH DECREASED AIR MOVEMENT AND WHEEZING. IT WAS ALSO NOTED THAT SHE SEEMED DISORIENTED AND CONFUSED. SISTER PROVIDED ADDITIONAL INFO BY PHONE SINCE PPT IS POOR HISTORIAN. DX WORKUP AND DONE PRIOR TO ADMISSION: ABNORMAL LABS OF SIGNIFICANCE; ELEVATED CRP- 12.3, WBC-12.75, POSITIVE UA, ABG 7.39/40/62; RADIOLOGY: CXR WITH BIBASILAR INTERSTITIAL DENSITIES, ANKLE, CT OF HEAD, AND US OF BLES. SHE WAS GIVEN ZOSYN, VANCOMYCIN, NARCAN, NEBULIZERS, SUPPLEMENTAL O2 VIA NASAL CANNULA, AND IV FLUIDS. <br  ADMITTED BY IM AND SEEN BY ORTHO AND ID. BC COLLECTED SAME DAY WAS POSITIVE FOR E. FAECALIS. IV ABX THERAPY AND HIV HANDLED BY ID. R ANKLE SYMPTOMS IMPROVED AFTER BEGINNING	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:23:02

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[Narrative](#)

Audit	User	Time (GMT)
ABX THERAPY. BC WERE NEGATIVE X 3 DAYS AFTER INITIAL DRAW (11/6/20). HOWEVER, HER HOSPITAL STAY WAS PROLONGED DUE PERSISTENT FEVER AND WORSENING MENTAL STATUS, WITH INCREASED LETHARGY AND EPISODES OF AGITATION. ADDITIONAL DIAGNOSTIC WORKUP WAS DONE TO RULE NEW INFECTIOUS PROCESSES. CONTINUOUS BEDSIDE EEG WAS ALSO DONE DUE TO HER AMS.  DISCHARGE SUMMARY UPDATE: ADMITTED FOR TREATMENT OF SEPSIS SECONDARY TO CELLULITIS AND GRAM POSITIVE BACTEREMIA, WHICH LATER GREW ENTEROCOCCUS FAECALIS.  US DVT BLE (11/25/2020): Negative for acute DVT in the bilateral lower extremities.' reason for change: New Information		
Query 'PV Query: Please provide any ankle imaging and results of BLE US.' answered with 'Radiological images were not included in medical records. results provided in narrative' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:12:46
Query '(1) PV Query: Please add medical history, DVT, COPD, smoke and schizophrenia, mentioned in narrative to subject's medical history.' answered with 'mh updated' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:20:05
Query ' PV Query: "GI bleed" was listed as the indication for pantoprazole. Please confirm if GI bleed was experienced and should be added as an AE/SAE or consider updating the indication (ie. GI bleed prophylaxis).' answered with 'indication updated to "prophylaxis for gi bleed"' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:16:12
User opened query '(1) PV Query: Please add medical history, DVT, COPD, smoke and schizophrenia, mentioned in narrative to subject's medical history.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 20:48:44
User opened query ' PV Query: "GI bleed" was listed as the indication for pantoprazole. Please confirm if GI bleed was experienced and should be added as an AE/SAE or consider updating the indication (ie. GI bleed prophylaxis).' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 20:47:57

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any ankle imaging and results of BLE US.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 20:45:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:41:26
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)	05 Jan 2021 16:41:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'discharge summary updated' (Site from Safety).	Junlin Long (b) (4)	04 Jan 2021 15:30:09
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:29:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT MISSED HER VISIT 2 APPOINTMENT TODAY. ATTEMPTED TO CONTACT MULTIPLE TIMES TODAY. CALLED EMERGENCY CONTACT AND HE STATED SHE WAS IN THE HOSPITAL FOR ABOUT 1.5 WEEKS DUE TO FOOT/ANKLE SURGERY. CONTACT PERSON WITH LIMITED KNOWLEDGE OF EVENTS.  UPDATE AFTER REVIEWING MEDICAL RECORDS:  HX OF RIGHT ANKLE FX APPROXIMATELY 3 MONTHS AGO, SEPT 2020. S/P R ANKLE ORIF 10/3/20. HAS NON-HEALING, DRAINING SURGICAL SCAR TO R ANKLE. MED HX: COPD, DVT, AIDS, BIPOLAR DISORDER, COPD, DIABETES, SEIZURES, AND A SMOKER.  PT. WENT TO ER ON 11/6, WITH RLE REDNESS, SWELLING, TENDERNESS, AND OPEN SURGICAL SCAR. ALSO C/O SEVERE PAIN TO R ANKLE X 10 DAYS PRIOR, AND WAS UNABLE TO SLEEP. INITIAL VS: B/P- 143/92, P-112, TEMP 99.9 ORAL. RESP-25, NAD, BUT WITH DECREASED AIR MOVEMENT AND WHEEZING. IT WAS ALSO NOTED THAT SHE SEEMED DISORIENTED AND CONFUSED. SISTER PROVIDED ADDITIONAL INFO BY PHONE SINCE PPT IS POOR HISTORIAN. DX WORKUP AND DONE PRIOR TO ADMISSION: ABNORMAL LABS OF SIGNIFICANCE; ELEVATED CRP- 12.3, WBC-12.75, POSITIVE UA, ABG 7.39/40/62; RADIOLOGY: CXR WITH BIBASILAR INTERSTITIAL DENSITIES, ANKLE, CT OF HEAD, AND US OF BLES. SHE WAS GIVEN ZOSYN, VANCOMYCIN, NARCAN, NEBULIZERS, SUPPLEMENTAL O2 VIA NASAL CANNULA, AND IV FLUIDS.  ADMITTED BY IM AND SEEN BY ORTHO AND ID. BC COLLECTED SAME DAY WAS POSITIVE FOR E. FAECALIS. IV ABX THERAPY AND HIV HANDLED BY ID. R ANKLE SYMPTOMS IMPROVED AFTER BEGINNING	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:29:33

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[Narrative](#)

Audit	User	Time (GMT)
ABX THERAPY. BC WERE NEGATIVE X 3 DAYS AFTER INITIAL DRAW (11/6/20). HOWEVER, HER HOSPITAL STAY WAS PROLONGED DUE PERSISTENT FEVER AND WORSENING MENTAL STATUS, WITH INCREASED LETHARGY AND EPISODES OF AGITATION. ADDITIONAL DIAGNOSTIC WORKUP WAS DONE TO RULE NEW INFECTIOUS PROCESSES. CONTINUOUS BEDSIDE EEG WAS ALSO DONE DUE TO HER AMS.  DISCHARGE SUMMARY update: admitted for treatment of sepsis secondary to cellulitis and gram positive bacteremia, which later grew enterococcus Faecalis.' reason for change: New Information		
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 'information added' (Site from Safety).	Junlin Long (b) (4) (b) (4)	04 Jan 2021 13:28:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	15 Dec 2020 11:50:00

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT MISSED HER VISIT 2 APPOINTMENT TODAY. ATTEMPTED TO CONTACT MULTIPLE TIMES TODAY. CALLED EMERGENCY CONTACT AND HE STATED SHE WAS IN THE HOSPITAL FOR ABOUT 1.5 WEEKS DUE TO FOOT/ANKLE SURGERY. CONTACT PERSON WITH LIMITED KNOWLEDGE OF EVENTS.  Update after reviewing medical records:  Hx of right ankle fx approximately 3 months ago, sept 2020. S/P R ankle ORIF 10/3/20. Has non-healing, draining surgical scar to R ankle. Med Hx: COPD, DVT, AIDS, bipolar disorder, COPD, diabetes, seizures, and a smoker.  Pt. went to ER on 11/6, with RLE redness, swelling, tenderness, and open surgical scar. Also c/o severe pain to R ankle x 10 days prior, and was unable to sleep. Initial VS: b/p- 143/92, p-112, temp 99.9 oral. Resp-25, NAD, but with decreased air movement and wheezing. It was also noted that she seemed disoriented and confused. Sister provided additional info by phone since ppt is poor historian. DX workup and done prior to admission: Abnormal labs of significance; elevated CRP- 12.3, WBC-12.75, positive UA, ABG 7.39/40/62; Radiology: CXR with bibasilar interstitial densities, ankle, CT of head, and US of BLEs. She was given Zosyn, Vancomycin, Narcan, nebulizers, supplemental O2 via nasal cannula, and IV fluids.  Admitted by IM and seen by Ortho and ID. BC collected same day was positive for E. Faecalis. IV abx therapy and HIV handled by ID. R ankle symptoms improved after beginning abx therapy. BC were negative x 3 days after initial draw (11/6/20). However, her hospital stay was prolonged due persistent fever and worsening mental status, with increased lethargy and episodes of agitation. Additional diagnostic workup was done to rule new infectious processes. Continuous bedside EEG was also done due to her AMS. Discharge summary unavailable at this time. Will update when available.'	Junlin Long (b) (4)	09 Dec 2020 20:34:50
reason for change: New Information		

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EAB) (1725)

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US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:09:34
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'covid-19 test was conducted on November 6th, 2020. result was "not detected by pcr".' (Site from Safety).	Junlin Long (b) (4)	08 Dec 2020 18:25:46
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:46:14
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:57
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)	24 Nov 2020 19:45:35
User entered 'participant missed her visit 2 appointment today. Attempted to contact multiple times today. Called emergency contact and he stated she was in the hospital for about 1.5 weeks due to foot/ankle surgery. Contact person with limited knowledge of events.'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 17:29:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 15:15:43
User entered '0'	System	18 Nov 2020 17:29:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 19:01:41
User entered 'USA-US085-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	09 Dec 2020 19:01:34

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Mental disorders NEC, PT: Mental status changes, LLT: Mental status changes - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 19:41:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	09 Dec 2020 19:41:10
Data point term sent to Coder	System	08 Dec 2020 18:28:36
Coding entries removed.	Junlin Long (b) (4)	08 Dec 2020 18:28:11
User entered 'ALTERED MENTAL STATUS (prolongation of hospitalization)' reason for change:	(b) (4)	
Data Entry Error	Junlin Long (b) (4)	08 Dec 2020 18:28:11
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Mental disorders NEC, PT: Mental status changes, LLT: Mental status changes - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 16:58:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Dec 2020 16:58:42
Data point term sent to Coder	System	08 Dec 2020 16:58:39
User entered 'Altered Mental Status'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '10 Nov 2020'	(b) (4), (b) (6)	08 Dec 2020 16:58:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:31:26
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:31:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:31:26
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 15:31:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved) for event altered mental status (prolongation of hospitalization), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 19:02:31
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved) for event altered mental status (prolongation of hospitalization), when available. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 14:59:40
Query 'PV Query: Please provide the hospital discharge date when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 14:59:29
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 14:55:34
User entered empty.	System	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	04 Jan 2021 15:32:07
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 by data change (Site from System).	System	04 Jan 2021 15:32:07
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
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	10 Dec 2020 17:55:38
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).	System	08 Dec 2020 17:00:41
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 by data change (Site from System).	System	08 Dec 2020 17:00:41
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	08 Dec 2020 16:58:08
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '06 Nov 2020'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:32:07
User entered '26 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 15:32:07
DataPoint Verified.	Junlin Long (b) (4)	04 Jan 2021 15:32:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Dec 2020 17:55:38
User entered empty; reason for change Data Entry Error	Junlin Long (b) (4)	10 Dec 2020 17:55:38
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 17:00:41
User entered 'un Nov 2020' (non-conformant).	(b) (4), (b) (6)	08 Dec 2020 17:00:41
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:32:07
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:32:07
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:32:07
User entered '7' reason for change: New Information	(b) (4)	04 Jan 2021 15:32:07
DataPoint Verified.	Junlin Long (b) (4)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:58:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:54:22
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:07
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:58:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:01:24
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'Bedside EEG monitoring was the Medical Treatment Procedure used for Altered Mental Status.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 16:24:29
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:58:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 16:58:08



US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'PV Query: Please provide the final event outcome for event altered mental status (prolongation of hospitalization), when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:42:20
Query 'PV Query: Please provide the final event outcome for event altered mental status (prolongation of hospitalization), when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'outcome updated' (Site from Safety).	Junlin Long (b) (4)	04 Jan 2021 15:31:37
DataPoint Un-verified.	(b) (4)	04 Jan 2021 15:31:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Junlin Long (b) (4)	04 Jan 2021 15:31:26
New Information	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome for event altered mental status (prolongation of hospitalization), when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 14:56:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per CDM Re-Query: Please confirm as this AE was not found. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:08:03
User closed query 'Per CDM Re-Query: Please confirm as this AE was not found. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:07:58
Query 'Per CDM Re-Query: Please confirm as this AE was not found. Thank you' answered with 'AE was added.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:09:52
Query 'Per CDM Re-Query: Please confirm as this AE was not found. Thank you' answered with 'AE was added.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:09:47
User opened query 'Per CDM Re-Query: Please confirm as this AE was not found. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:03:47
User closed query 'Per DM CLR: Narrative = EVIDENCE OF CORTICAL DYSFUNCTION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:03:47
User opened query 'Per CDM Re-Query: Please confirm as this AE was not found. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:03:22
User closed query 'Per DM CLR: Narrative = MILD DIFFUSE ENCEPHALOPATHY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:03:22
Query 'Per DM CLR: Narrative = EVIDENCE OF CORTICAL DYSFUNCTION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Evidence of Cortical Dysfunction was recorded as a separate AE. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 16:16:43

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = MILD DIFFUSE ENCEPHALOPATHY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Mild Diffuse Encephalopathy was recorded as a separate AE. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 16:16:19
User opened query 'Per DM CLR: Narrative = EVIDENCE OF CORTICAL DYSFUNCTION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:58:48
User opened query 'Per DM CLR: Narrative = MILD DIFFUSE ENCEPHALOPATHY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:58:41
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:35:49

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT WAS ADMITTED TO THE HOSPITAL NOVEMBER 6, 2020 FOR SIGNIFICANT RIGHT ANKLE CELLULITIS. PARTICIPANT'S MEDICAL HISTORY INCLUDES COPD, BI-POLAR DISORDER, SCHIZOPHRENIA, SEIZURES. AT ADMISSION SHE WAS NOTED TO HAVE INTERMITTENT CONFUSION AND LETHARGY. DURING HER HOSPITAL ADMISSION SHE HAD A PROGRESSION IN HER LETHARGY WITH PERIODS OF AGGRESSION. A CT AND AN MRI OF THE BRAIN BOTH WITHOUT IV CONTRAST PERFORMED 11/10/2020 SHOWED NO INTRACRANIAL ABNORMALITY: NEGATIVE EXAMS. CONTINUOUS VIDEO EEG STARTED ON 11/11/2020 SHOWED MILD DIFFUSE ENCEPHALOPATHY, BUT NO EPILEPTIFORM DISCHARGES WERE SEEN, AND NO SEIZURES. ON 11/16/2020 THERE WAS EVIDENCE OF SEVERE DIFFUSE ENCEPHALOPATHY; ON 11/17/2020 THERE WAS EVIDENCE OF CORTICAL DYSFUNCTION. A REPEAT CT OF THE BRAIN WAS ALSO DONE AND WAS STILL NEGATIVE FOR INTRACRANIAL ABNORMALITIES. A LUMBAR PUNCTURE PERFORMED 11/15/2020 WAS NEGATIVE FOR MENINGITIS.  Neurologist thought the altered mental status could possibly be acute metabolic encephalopathy.' reason for change: New Information DataPoint Verified.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:35:49
	(b) (4), (b) (6)	15 Dec 2020 11:50:00

US3622282

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT WAS ADMITTED TO THE HOSPITAL NOVEMBER 6, 2020 FOR SIGNIFICANT RIGHT ANKLE CELLULITIS. PARTICIPANT'S MEDICAL HISTORY INCLUDES COPD, BI-POLAR DISORDER, SCHIZOPHRENIA, SEIZURES. AT ADMISSION SHE WAS NOTED TO HAVE INTERMITTENT CONFUSION AND LETHARGY. DURING HER HOSPITAL ADMISSION SHE HAD A PROGRESSION IN HER LETHARGY WITH PERIODS OF AGGRESSION. A CT and an MRI OF THE BRAIN both WITHOUT IV CONTRAST PERFORMED 11/10/2020 SHOWED NO INTRACRANIAL ABNORMALITY: NEGATIVE EXAMs. CONTINUOUS VIDEO EEG STARTED ON 11/11/2020 SHOWED MILD DIFFUSE ENCEPHALOPATHY, BUT NO EPILEPTIFORM DISCHARGES WERE SEEN, AND NO SEIZURES. ON 11/16/2020 THERE WAS EVIDENCE OF SEVERE DIFFUSE ENCEPHALOPATHY; ON 11/17/2020 THERE WAS EVIDENCE OF CORTICAL DYSFUNCTION. A repeat CT of the brain was also done and was still negative for intracranial abnormalities. A LUMBAR PUNCTURE PERFORMED 11/15/2020 WAS NEGATIVE FOR MENINGITIS. ADDITIONAL INFORMATION WILL BE PROVIDED AS OBTAINED.' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 17:19:20

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient was admitted to the hospital November 6, 2020 for significant right ankle cellulitis. Participant's medical history includes COPD, bi-polar disorder, schizophrenia, seizures. At admission she was noted to have intermittent confusion and lethargy. During her hospital admission she had a progression in her lethargy with periods of aggression. A CT of the brain without IV contrast that was was performed 11/10/2020 showed no intracranial abnormality; negative exam. Continuous video EEG started on 11/11/2020 showed mild diffuse encephalopathy, but no epileptiform discharges were seen, and no seizures. On 11/16/2020 there was evidence of severe diffuse encephalopathy; on 11/17/2020 there was evidence of cortical dysfunction. A lumbar puncture performed 11/15/2020 was negative for meningitis. Additional information will be provided as obtained.'	(b) (4), (b) (6)	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 16:58:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 16:58:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 15:32:07
User entered '0'	System	08 Dec 2020 16:58:08

US3622282

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Acute cystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:01:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:01:41
Data point term sent to Coder	System	04 Jan 2021 15:37:45
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:37:40
Coding entries removed.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:37:40
User entered 'acute cystitis without hematuria' reason for change: New Information	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:37:40
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 18:19:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 18:19:58
Data point term sent to Coder	System	09 Dec 2020 18:19:13
User entered 'Urinary tract infection'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '4 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:19:01

US3622282

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:37:40
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:37:40
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 18:19:01

US3622282

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:37:40
User entered '13 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 15:37:40
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:19:01
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

US3622282

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 18:19:01
	(b) (4)	



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

US3622282

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	26 Jan 2021 15:15:11
User entered '1' reason for change: Per Query Resolution	Junlin Long (b) (4)	26 Jan 2021 15:15:11
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 18:19:01

US3622282

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 03:45:32
Query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:15:16
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:15:11
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:15:11
User opened query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:12:06
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '1'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

US3622282

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:37:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Junlin Long (b) (4)	04 Jan 2021 15:37:40
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4)	09 Dec 2020 18:19:01
	(b) (4)	



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 18:19:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:03:20
User entered 'USA-US085-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	05 Jan 2021 16:44:47

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'PV Query: Please reconcile the events, hypotension, since both have the same start date. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:30:44
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 23:09:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 23:09:02
Query 'PV Query: Please reconcile the events, hypotension, since both have the same start date. ' answered with 'Data entry error. AE (2nd episode) was updated and corrected.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:37:08
Data point term sent to Coder	System	05 Mar 2021 15:34:28
User entered 'HYPOTENSION (1ST EPISODE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:34:27
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 15:33:43
User entered 'HYPOTENSION (1st edisode)' reason for change: New Information	(b) (4), (b) (6)	05 Mar 2021 15:33:43
User opened query 'PV Query: Please reconcile the events, hypotension, since both have the same start date. ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 07:18:33
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 15:51:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 15:51:29
Data point term sent to Coder	System	04 Jan 2021 15:50:51
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:50:16
Coding entries removed.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:50:16
User entered 'HYPOTENSION' reason for change: New Information	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 19:49:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 19:49:57
Data point term sent to Coder	System	09 Dec 2020 18:22:15
User entered 'hypotension (one episode)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 19:14:40
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:14:40
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '10 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:39:52
User entered '13 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 15:39:52
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '10 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 18:21:57
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:21:57
	(b) (4)	



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:39:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	04 Jan 2021 15:39:52
reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:39:52
DataPoint Verified.	(b) (4)	15 Dec 2020 11:50:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Dec 2020 11:50:00
	Junlin Long (b) (4)	09 Dec 2020 18:21:57
	(b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:50:16
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 18:21:57
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:50:16
User entered '1' reason for change: New Information	(b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	Junlin Long (b) (4)	15 Dec 2020 11:50:00
User entered '0'	(b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:50:16
User entered '6 Nov 2020' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:50:16
User entered '26 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:21:57
	(b) (4)	



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:50:16
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:50:16
User entered '7' reason for change: New Information	(b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	Junlin Long (b) (4)	15 Dec 2020 11:50:00
User entered empty.	(b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:55:30
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:15
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:16:41
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	Junlin Long (b) (4)	09 Dec 2020 18:21:57



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'I'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 18:21:57
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:21:57

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'PV Query: Start date for current condition, schizophrenia is missing in medical history. Please provide, and if not available please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:36:52
User closed query 'PV Query: Start date for current condition, chronic obstructive pulmonary disease (COPD) is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:36:47
User closed query 'PV Query: End date for current condition, deep vein thrombosis (DVT) is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:36:31
User closed query 'PV Query: Start date for current condition, smoker is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:36:18
User closed query 'PV Query: Start date for current condition, seizure is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:36:11
User closed query 'PV Query: Start date for current condition, diabetes is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:36:05
Query 'PV Query: Start date for current condition, schizophrenia is missing in medical history. Please provide, and if not available please state so.' answered with 'Schizophrenia start date is unknown as per participant. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 17:00:32
Query 'PV Query: Start date for current condition, chronic obstructive pulmonary disease (COPD) is missing in medical history. Please provide, and if not available please state so. ' answered with 'COPD start date is unknown as per participant. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 17:00:23

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: End date for current condition, deep vein thrombosis (DVT) is missing in medical history. Please provide, and if not available please state so. ' answered with 'DVT end date is 11/6/2020 according to hospital records. Medical History has been updated.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 16:46:38
Query 'PV Query: Start date for current condition, smoker is missing in medical history. Please provide, and if not available please state so. ' answered with 'Participant has a history of smoking since 1980. Medical history has been updated. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 16:32:00
Query 'PV Query: Start date for current condition, seizure is missing in medical history. Please provide, and if not available please state so. ' answered with 'Seizure start date is unknown. Participant is not a good historian. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 16:27:44
Query 'PV Query: Start date for current condition, diabetes is missing in medical history. Please provide, and if not available please state so. ' answered with 'Diabetes start date is unknown as per participant. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 16:26:40
User opened query 'PV Query: Start date for current condition, schizophrenia is missing in medical history. Please provide, and if not available please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:26:45
User opened query 'PV Query: Start date for current condition, chronic obstructive pulmonary disease (COPD) is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:26:26
User opened query 'PV Query: End date for current condition, deep vein thrombosis (DVT) is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:26:05
User opened query 'PV Query: Start date for current condition, smoker is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:25:54

US3622282

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Start date for current condition, seizure is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:25:25
User opened query 'PV Query: Start date for current condition, diabetes is missing in medical history. Please provide, and if not available please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:25:10
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:50:16
User entered 'A couple rapid responses were called throughout her stay for febrile episodes with significant hypotension requiring fluid resuscitation.' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:50:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:21:57



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 15:50:16
User entered '0'	System	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 18:21:57

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 15:50:16

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal skin infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:02:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:02:52
Data point term sent to Coder	System	09 Dec 2020 18:24:17
User entered 'fungal infection (bilateral inguinal areas)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 18:21:27
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Feb 2021 18:21:27
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '12 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:50:29
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	07 Apr 2021 15:00:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 14:45:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 14:45:20
User entered 'UN Dec 2020' (non-conformant).	(b) (4), (b) (6)	07 Apr 2021 14:45:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 14:45:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 14:45:07
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 14:45:07
User entered ' Dec 2020' (non-conformant).	(b) (4), (b) (6)	07 Apr 2021 14:45:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 12:25:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 12:25:31
User entered 'UN Dec 2020' (non-conformant).	(b) (4), (b) (6)	24 Feb 2021 12:25:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Feb 2021 18:25:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Feb 2021 18:25:01
User entered '00 Dec 2020' (non-conformant).	(b) (4), (b) (6)	23 Feb 2021 18:25:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Feb 2021 18:21:27
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 18:21:27
User entered 'un Dec 2020' (non-conformant).	(b) (4), (b) (6)	22 Feb 2021 18:21:27
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:23:33
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 18:23:33
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33



US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'I'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Per CDM: Per sponsor review, end date is provided but outcome is unknown. Please review. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:44:46
Query 'Per CDM: Per sponsor review, end date is provided but outcome is unknown. Please review. ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 15:53:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:50:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	15 Apr 2021 15:50:29
Data Entry Error		
User opened query 'Per CDM: Per sponsor review, end date is provided but outcome is unknown. Please review. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:45:28
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 18:23:33

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 18:23:33

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal skin infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:03:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:03:33
Data point term sent to Coder	System	04 Jan 2021 13:20:44
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 13:19:49
Coding entries removed.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 13:19:49
User entered 'FUNGAL INFECTION (PANNUS FOLD)' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	04 Jan 2021 13:19:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal skin infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:12:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:12:51
Data point term sent to Coder	System	09 Dec 2020 18:25:20
User entered 'fungal infection (pannus fold)	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	15 Apr 2021 15:51:51
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:51:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 15:51:51
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	15 Apr 2021 15:51:36
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:04:45
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE is ongoing but recovering.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 18:26:50
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:59:40
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '12 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:55:46
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:23
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:20:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	Junlin Long (b) (4)	09 Dec 2020 18:24:56



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '1'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Per CDM: Per sponsor review, please confirm outcome is unknown. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:44:23
Query 'Per CDM: Per sponsor review, please confirm outcome is unknown. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 15:51:48
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 15:51:36
User opened query 'Per CDM: Per sponsor review, please confirm outcome is unknown. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:47:44
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

US3622282

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 18:24:56

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 18:24:56



US3622282

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Skin fissures, LLT: Skin fissure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:10:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:10:56
Data point term sent to Coder	System	09 Dec 2020 18:26:22
User entered 'fissure intergluteal fold'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:26:21

US3622282

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 18:01:07
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 18:01:07
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21



US3622282

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 12:27:34
User entered '12 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	21 Apr 2021 12:27:34
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	07 Apr 2021 15:00:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Feb 2021 18:01:07
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 18:01:07
User entered 'un Dec 2020' (non-conformant).	(b) (4), (b) (6)	22 Feb 2021 18:01:07
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:26:21
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

US3622282

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'I'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

US3622282

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per sponsor review, end date is provided but outcome. Please review outcome. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 04:42:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
Query 'Per CDM: Per sponsor review, end date is provided but outcome. Please review outcome. ' answered with 'Outcome has been provided' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:27:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 12:27:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	21 Apr 2021 12:27:34
User opened query 'Per CDM: Per sponsor review, end date is provided but outcome. Please review outcome. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:46:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:26:21



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 18:26:21

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 18:26:21

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 16:05:25
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' answered with 'Symptom cause is undetermined. Participant has multiple underlying conditions that may have caused this AE including but limited to Asthma, COPD, bilateral opacities on lower lobes. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 18:37:10
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:59:56
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 05:50:42
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'this subject was not assessed for potential COVID-19 infection.' (Site from DM).	Junlin Long (b) (4) (b) (4)	03 Feb 2021 16:55:12
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:37:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:22:34

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 23:22:34
Data point term sent to Coder	(b) (4)	04 Jan 2021 15:52:52
DataPoint Un-verified.	System	04 Jan 2021 15:52:17
	Junlin Long (b) (4)	04 Jan 2021 15:52:17
	(b) (4)	
Coding entries removed.	Junlin Long (b) (4)	04 Jan 2021 15:52:17
	(b) (4)	
User entered 'intermittent WHEEZING' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 15:52:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 11:50:00
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 18:55:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 18:55:00
Data point term sent to Coder	(b) (4)	
User entered 'wheezing'	System	09 Dec 2020 18:52:55
	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:52:17
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 15:52:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '6 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 18:52:25

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 15:52:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: New Information	(b) (4)	04 Jan 2021 15:52:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25



US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:56:05
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:33
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:21:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	Junlin Long (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

US3622282

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'I'	Junlin Long (b) (4)	09 Dec 2020 18:52:25
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 18:52:25

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 18:52:25

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Lethargy, LLT: Lethargy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 19:51:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 19:51:02
Data point term sent to Coder	System	09 Dec 2020 19:49:47
User entered 'lethargy'	Junlin Long (b) (4)	09 Dec 2020 19:49:44
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44



US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 16:07:25
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Mar 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Mar 2021 16:07:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Mar 2021 16:07:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Mar 2021 16:07:25
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 16:07:25
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 19:49:44



US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44



US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4)	09 Dec 2020 19:49:44
	(b) (4)	



US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'I'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 16:07:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	02 Mar 2021 16:07:51
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:50:00
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Dec 2020 19:49:44

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 19:49:44

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hypoglycaemic conditions NEC, PT: Hypoglycaemia, LLT: Hypoglycemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 15:56:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 15:56:29
Data point term sent to Coder	System	04 Jan 2021 15:55:55
User entered 'hypoglycemia'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '16 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29



US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29



US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:56:28
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:42
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4)	07 Jan 2021 14:22:33
User entered 'None (NONE)'	Junlin Long (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:55:29

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 15:55:29



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 15:55:29

US3622282

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Atelectasis, LLT: Atelectasis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 15:58:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	04 Jan 2021 15:58:31
Data point term sent to Coder	System	04 Jan 2021 15:57:57
User entered 'atelectasis'	Junlin Long (b) (4)	04 Jan 2021 15:57:36
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 15:57:36



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

US3622282

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

US3622282

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

US3622282

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

US3622282

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:56:48
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:46
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4)	07 Jan 2021 14:28:56
User entered 'None (NONE)'	Junlin Long (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

US3622282

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 05:35:30
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Con Med has been updated to match this AE.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:08:29
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:55:53
User entered 'I'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

US3622282

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Per CDM: Per sponsor review, please confirm if outcome is unknown. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:20:24
Query 'Per CDM: Per sponsor review, please confirm if outcome is unknown. ' answered with 'Outcome is unknown. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:47:36
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:47:09
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 14:46:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:46:36
User opened query 'Per CDM: Per sponsor review, please confirm if outcome is unknown. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:46:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 15:57:36

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'USA-US085-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	05 Jan 2021 16:45:31

US3622282

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 23:09:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	05 Mar 2021 23:09:01
Data point term sent to Coder	System	05 Mar 2021 15:38:36
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 15:37:36
User entered 'HYPOTENSION (2nd episode)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:37:36
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 16:01:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	04 Jan 2021 16:01:28
Data point term sent to Coder	System	04 Jan 2021 16:00:58
User entered 'hypotension'	Junlin Long (b) (4)	04 Jan 2021 16:00:13
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

US3622282

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:35:43
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 13:13:34
User entered '21 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '23 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13



US3622282

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

US3622282

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '26 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

US3622282

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:57:01
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:51
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4)	07 Jan 2021 14:34:51
User entered 'None (NONE)'	Junlin Long (b) (4)	04 Jan 2021 16:00:13

US3622282

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

US3622282

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #70 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:39:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #70 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'Start date of Hypotension was corrected to reflect medical records. AE was updated on participant's chart.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 13:13:24
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #70 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:57:22
User entered 'I'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'A couple rapid responses were called throughout her stay for febrile episodes with significant hypotension requiring fluid resuscitation.'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 16:00:13

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 16:00:13

US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Dysphagia, LLT: Swallowing difficult - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:03:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:03:28
Data point term sent to Coder	System	04 Jan 2021 16:02:59
User entered 'difficulty swallowing'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '16 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '22 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01



US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01



US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:57:21
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:55
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4)	07 Jan 2021 14:35:31
User entered 'None (NONE)'	Junlin Long (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 17:14:16
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

US3622282

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 05:27:16
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Data entry Error. No ConMeds were given for this AE' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:14:51
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 17:14:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:57:35
User entered '1'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:02:01

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 16:02:01



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 16:02:01

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:27:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:27:34
Data point term sent to Coder	System	04 Jan 2021 17:45:45
User entered 'right ankle cellulitis'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:45:15



US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:30:52
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'AE ongoing' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 18:08:05
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:57:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:45:15
	(b) (4)	

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:57:43
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'participant had only one dose of ip and missed the second dose, so "None" should be selected as per protocol.' (Site from DM).	Junlin Long (b) (4)	25 Jan 2021 21:46:59
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4)	07 Jan 2021 14:38:13
User entered 'None (NONE)'	Junlin Long (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:45:15
	(b) (4)	

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'No medical treatment procedure or non-drug therapy was performed for this AE. ' (Site from DM). User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 05:41:20
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'No medical treatment procedure or non-drug therapy was performed for this AE. ' (Site from DM). User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 18:20:56
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User entered '1'	(b) (4), (b) (6)	25 Feb 2021 18:18:03
	(b) (4), (b) (6)	10 Feb 2021 00:58:03
	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 17:45:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 17:45:15

US3622282

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Agitation, LLT: Agitation - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 18:08:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 18:08:52
Data point term sent to Coder	System	26 Jan 2021 15:12:45
User entered 'episodes of agitation'	Junlin Long (b) (4)	26 Jan 2021 15:12:28
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4)	26 Jan 2021 15:12:28
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '14 Nov 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

US3622282

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

US3622282

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

US3622282

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

US3622282

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28



US3622282

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

US3622282

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 15:12:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Jan 2021 15:12:28

US3622282

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis of bone - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:09:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:09:07
Data point term sent to Coder	System	26 Jan 2021 16:28:10
User entered 'chronic avascular necrosis of distal femur and proximal tibia'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

US3622282

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 16:27:27



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

US3622282

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

US3622282

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

US3622282

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

US3622282

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	Junlin Long (b) (4)	26 Jan 2021 16:27:27



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

US3622282

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 09:10:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Jan 2021 16:27:27

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 18:09:05
User entered 'USA-US085-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	27 Jan 2021 18:08:30



US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:10:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:10:09
Data point term sent to Coder	System	27 Jan 2021 16:09:50
User entered 'sepsis'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 17:37:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 17:37:06
User entered '25 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4)	22 Feb 2021 17:37:06
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 16:09:28
User entered empty.	Junlin Long (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 17:37:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 17:37:06
User entered 'No (N)' reason for change: Per Query Resolution	Junlin Long (b) (4)	22 Feb 2021 17:37:06
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 16:09:28
User entered empty.	Junlin Long (b) (4)	27 Jan 2021 16:09:28



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '31 Jan 2021' reason for change: New Information	Junlin Long (b) (4)	22 Feb 2021 17:37:06
User entered empty.	Junlin Long (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Per CDM Re-Query: Please keep Query open until resolution ' canceled (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:09:23
	(b) (4), (b) (6)	24 Mar 2021 11:04:25
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)	09 Mar 2021 04:53:41
User opened query 'Per CDM Re-Query: Please keep Query open until resolution ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:38:00
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 'We are pending medical records from hospital. Request for her records has been submitted twice.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 13:22:06
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	27 Jan 2021 16:09:28
User entered 'I'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28



US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm action taken as the subject only received 1 dose of Placebo (on 21 Oct 2020) prior to event.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:27:52
Query 'PV Query: Please confirm action taken as the subject only received 1 dose of Placebo (on 21 Oct 2020) prior to event.' answered with 'The participant just received one dose. Per protocol, it should be "None".' (Site from Safety).	Junlin Long (b) (4)	21 Apr 2021 12:38:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'PV Query: Please confirm action taken as the subject only received 1 dose of Placebo (on 21 Oct 2020) prior to event.' (Site from Safety).	(b) (4), (b) (6)	14 Mar 2021 16:36:30
User entered 'None (NONE)'	Junlin Long (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Jan 2021 16:09:28
User entered '0'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 17:37:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 17:37:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Junlin Long (b) (4)	22 Feb 2021 17:37:06
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 16:09:28
User entered empty.	Junlin Long (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	05 Apr 2021 00:08:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:23:34
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:23:29
User closed query 'PV Query: Please provide start date for event.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 21:23:20
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'provided' (Site from Safety).	Junlin Long (b) (4)	22 Feb 2021 17:38:47
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'provided' (Site from Safety).	Junlin Long (b) (4)	22 Feb 2021 17:38:39
Query 'PV Query: Please provide start date for event.' answered with 'provided' (Site from Safety).	Junlin Long (b) (4)	22 Feb 2021 17:38:30
User opened query 'PV Query: Please provide event details for 2nd mention of sepsis. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:20:31
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:20:20
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:20:03
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:19:49
User opened query 'PV Query: Please provide start date for event.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:19:34

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EAB) (1725)

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**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital admission date ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:19:24
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Jan 2021 16:09:28
User entered empty.	Junlin Long (b) (4) (b) (4)	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 16:09:28

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Jan 2021 16:09:28

US3622282

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Per DM CLR: Please note this AE overlaps with AE #18. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:55:25
User coded data point as SOC: Nervous system disorders, HLT: Encephalopathies, HLT: Encephalopathies NEC, PT: Encephalopathy, LLT: Encephalopathy - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 03:53:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 03:53:02
Data point term sent to Coder	System	07 Apr 2021 15:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:33:55
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 15:33:55
User entered 'DIFFUSE ENCEPHALOPATHY' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:33:55
Query 'Per DM CLR: Please note this AE overlaps with AE #18. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' answered with 'AEs will be reconciled.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:32:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Nervous system disorders, HLT: Encephalopathies, HLT: Encephalopathies NEC, PT: Encephalopathy, LLT: Encephalopathy - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 09:45:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 09:45:46
User opened query 'Per DM CLR: Please note this AE overlaps with AE #18. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:11:05
Data point term sent to Coder	System	25 Feb 2021 17:20:51
User entered 'Severe Diffuse Encephalopathy'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:33:55
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:33:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '17 Nov 2020'	(b) (4), (b) (6)	25 Feb 2021 17:20:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 17:15:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '25 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 17:15:52
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

US3622282

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Query 'Per MM: please confirm seriousness assessment.' answered with 'Confirmed according to records.' (Site from DM).	Junlin Long (b) (4) (b) (4)	03 May 2021 13:30:25
User opened query 'Per MM: please confirm seriousness assessment.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 15:34:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

US3622282

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

US3622282

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Apr 2021 15:42:42
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:42:42
User entered '1' reason for change: New Information	(b) (4), (b) (6)	07 Apr 2021 15:42:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Apr 2021 15:42:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

US3622282

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:20:08

US3622282

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'No procedures were performed for this AE' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:29:08
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'No procedures were performed for this AE' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:43:44
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:42:34
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:42:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User entered '1'	(b) (4), (b) (6)	19 Mar 2021 01:11:12
	(b) (4), (b) (6)	25 Feb 2021 17:20:08



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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:15:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 17:15:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 17:15:52
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:20:08
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 17:20:08

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 17:20:08

US3622282

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Cortical dysfunction NEC, PT: Right hemisphere deficit syndrome, LLT: Right hemisphere deficit syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:36:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:36:32
Data point term sent to Coder	System	25 Feb 2021 18:03:54
User entered 'Evidence of Bilateral Cortical Dysfunction (Max Right Hemisphere)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

US3622282

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '18 Nov 2020'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:03:53



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

US3622282

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

US3622282

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

US3622282

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53



US3622282

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 18:03:53



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 18:03:53

US3622282

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 18:04:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 18:04:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 18:04:45
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 18:03:53
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 18:03:53

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:19:12
User entered 'USA-US085-2021-mRNA-1273-P301000014'	System	01 Mar 2021 15:19:06
User entered 'New'	(b) (4), (b) (6)	01 Mar 2021 15:19:06



US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Bone infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:33:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 14:33:51
Data point term sent to Coder	System	26 Feb 2021 14:32:41
User entered 'bone infection'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '25 Feb 2021'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 14:32:17

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:59:15
	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Feb 2021 14:32:17
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4)	26 Feb 2021 14:32:17
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:06:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:45:18
User entered empty.	System	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4)	26 Feb 2021 14:32:17

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
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)	01 Mar 2021 09:10:06
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 'Participant as of today is still admitted to hospital. ' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 17:17:29
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	26 Feb 2021 14:32:17
User entered 'I'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '25 Feb 2021'	Junlin Long (b) (4)	26 Feb 2021 14:32:17
	(b) (4)	

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:38:18
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:27:13
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'Still pending medical records. Request has been sent. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 12:29:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:47:56
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4)	26 Feb 2021 14:32:17
	(b) (4)	

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 01:11:43
	Junlin Long (b) (4)	26 Feb 2021 14:32:17
	(b) (4)	

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:46:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Feb 2021 14:32:17

US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Per DM CLR: Narrative = SHE REPORTED SHE RECEIVED IV ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:11:37
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:51:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:51:32
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:48:21
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)	08 Mar 2021 18:47:13



US3622282

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 10 Jun 2021 09:10:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:45:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 14:35:08
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Feb 2021 14:35:08
User entered 'participant called and reported she was admitted to hospital on 25FEB2021 for bone infection. she reported she received iv antibiotics. she does not know names or doses of antibiotics. will update once medical records are obtained.' reason for change: Per Query Resolution	Junlin Long (b) (4)	26 Feb 2021 14:35:08
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 14:32:17
User entered empty.	Junlin Long (b) (4)	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 14:32:17

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 14:32:17

US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 01:04:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 01:04:48
Data point term sent to Coder	System	03 Mar 2021 13:54:34
User entered 'HYPOCALCEMIA (2nd episode)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 13:53:47
User entered 'HYPOCALCEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:30:26
Data point term sent to Coder	System	02 Mar 2021 18:30:10
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 18:30:10
User entered 'HYPOCALEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:30:10
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 19:09:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 19:09:53
Data point term sent to Coder	System	26 Feb 2021 19:09:23
User entered 'Hypocalcemia'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '10 Nov 2020'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '14 Nov 2020'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26



US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		02 Mar 2021 16:14:36
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	02 Mar 2021 16:12:02
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		02 Mar 2021 16:09:14
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	26 Feb 2021 19:10:16
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		26 Feb 2021 19:09:09
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	26 Feb 2021 19:08:55
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 08:45:55
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Participant not admitted to hospital secondary to this AE. ' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 16:15:21
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 Mar 2021 16:14:36
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 16:14:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Mar 2021 16:12:02
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 Mar 2021 16:12:02
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 16:12:02
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 Mar 2021 16:09:14
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:09:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	26 Feb 2021 19:10:16
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	26 Feb 2021 19:10:16

US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:10:16
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	26 Feb 2021 19:09:09
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).	System	26 Feb 2021 19:09:09
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 by data change (Site from System).	System	26 Feb 2021 19:09:09
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:09:09
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	26 Feb 2021 19:08:55
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	26 Feb 2021 19:08:55
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	26 Feb 2021 19:08:55
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 19:08:55
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	26 Feb 2021 19:08:26
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:14:36
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:12:02
User entered empty; reason for change New Information	(b) (4), (b) (6)	02 Mar 2021 16:09:14
User entered '06 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 19:09:47
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:08:26

US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:14:36
User entered '25 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:12:02
User entered empty; reason for change New Information	(b) (4), (b) (6)	02 Mar 2021 16:09:14
User entered '25 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 19:09:47
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:15:48
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:08:26

US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26



US3622282

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #46 indication is CALCIUM REPLACEMENT. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:28:31
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #46 indication is CALCIUM REPLACEMENT. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'Appropriate match has been made for this AE.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #46 indication is CALCIUM REPLACEMENT. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:12:02
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 19:08:26

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 19:08:26



US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:30:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:30:51
Data point term sent to Coder	System	02 Mar 2021 18:30:10
User entered 'HYPOKALEMIA' reason for change:	(b) (4), (b) (6)	02 Mar 2021 18:29:56
Data Entry Error		
Data point term sent to Coder	System	02 Mar 2021 17:02:06
User entered 'Hypokalcemia'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '17 Nov 2020'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:02:00



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '18 Nov 2020'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00



US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:02:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:02:18
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 17:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:02:00
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00



US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:02:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:02:18
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 17:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:02:00
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:02:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:02:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 17:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:02:00
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' canceled (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 19:55:33
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:12:26
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:19:47
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:02:00



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 17:02:00

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 17:02:00

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypomagnesaemia, LLT: Hypomagnesemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:54:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:54:43
Data point term sent to Coder	System	02 Mar 2021 17:54:15
User entered 'Hypomagnesemia'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '12 Nov 2020'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '13 Nov 2020'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' canceled (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 19:55:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 01:12:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:19:27
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	02 Mar 2021 17:53:22



US3622282

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 10 Jun 2021 09:10:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 17:53:22

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 17:53:22

US3622282

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypomagnesaemia, LLT: Hypomagnesemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:48:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:48:47
Data point term sent to Coder	System	02 Mar 2021 18:19:48
User entered 'Hypomagnesemia (2nd episode)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '16 Nov 2020'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '24 Nov 2020'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05



US3622282

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

US3622282

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05

US3622282

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05



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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 18:19:05



US3622282

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' canceled (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 19:56:32
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' (Site from DM). User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 01:12:53
	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 18:19:05

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 10 Jun 2021 09:10:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:53:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:53:58
Data point term sent to Coder	System	03 Mar 2021 13:53:34
User entered 'Hypocalcemia'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '06 Nov 2020'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '09 Nov 2020'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04



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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04



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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04



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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '1'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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Folder: Adverse Events

Form: Adverse Events (26)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 13:53:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 13:53:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 13:53:21
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 13:53:14
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:10:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

**US3622282**

**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04



US3622282

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 10 Jun 2021 09:10:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 13:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Mar 2021 13:52:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Mar 2021 18:41:04

US3622282

Folder: Adverse Events

Form: Adverse Events (27)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 01:05:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 01:05:47
Data point term sent to Coder	System	03 Mar 2021 14:07:47
User entered 'Hypocalcemia (3rd episode)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

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**Form: Adverse Events (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '23 Nov 2020'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51



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**Folder: Adverse Events**

**Form: Adverse Events (27)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

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**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

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**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '24 Nov 2020'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (27)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (27)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:06:51

**US3622282**

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

US3622282

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51



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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

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**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51

US3622282

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51

US3622282

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51



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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

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**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:06:51

US3622282

Folder: Adverse Events

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Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:06:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 14:06:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 14:06:57
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:06:51
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51



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**Folder: Adverse Events**

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**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:06:51

**US3622282**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 14:06:51

**US3622282**

**Folder: Adverse Events**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 14:06:51

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 01:05:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 01:05:49
Data point term sent to Coder	System	03 Mar 2021 14:09:47
User entered 'Hypokalemia (2nd episode)'	(b) (4), (b) (6) (b) (4)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04



US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '23 Nov 2020'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '26 Nov 2020'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04



US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04



US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '1'	(b) (4), (b) (6)	03 Mar 2021 14:09:04



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 14:09:04

US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:09:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 14:09:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 14:09:10
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:09:04
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

US3622282

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 10 Jun 2021 09:10:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 14:09:04

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 14:09:04

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Electrolyte imbalance NEC, PT: Electrolyte imbalance, LLT: Electrolyte imbalance - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:34:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:34:52
Data point term sent to Coder	System	05 Mar 2021 16:18:46
User entered 'Electrolyte Imbalance'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '06 Nov 2020'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '26 Nov 2020'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Mar 2021 16:18:46

US3622282

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 10 Jun 2021 09:10:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 16:18:46

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 16:18:46



US3622282

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:22:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 16:22:54
Data point term sent to Coder	System	05 Mar 2021 16:21:49
User entered 'Constipation'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '24 Nov 2020'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '26 Nov 2020'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

US3622282

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15

US3622282

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 09:10:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15

US3622282

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

US3622282

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 10 Jun 2021 09:10:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:04:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:21:15



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 16:21:15

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 16:21:15

US3622282

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain ankle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:13:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:13:25
Data point term sent to Coder	System	07 Apr 2021 14:41:18
User entered 'severe right ankle pain'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

US3622282

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

US3622282

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '27 Oct 2020'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

US3622282

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	07 Apr 2021 14:41:20
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	07 Apr 2021 14:41:08
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

US3622282

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
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).		07 Apr 2021 14:41:20
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 by data change (Site from System).		07 Apr 2021 14:41:20
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:41:20
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		07 Apr 2021 14:41:08
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).		07 Apr 2021 14:41:08
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	07 Apr 2021 14:41:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:41:08
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	07 Apr 2021 14:40:48
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

US3622282

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

**Hospital Discharge Date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:41:20
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48

US3622282

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 10 Jun 2021 09:10:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:41:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Apr 2021 14:40:48



**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:33
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 14:40:48

**US3622282**

**Folder: Adverse Events**

**Form: Adverse Events (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 14:40:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:10:09

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:26
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 09:45:26
Query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'updated; please refer to conmed line 77.' (Site from DM).	Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:33:43
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 08:15:49
Query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 03:12:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:10:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever &gt; 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:03:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:51:59
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:17:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:21:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:21:44
Data point term sent to Coder	System	21 Oct 2020 17:20:22
User entered 'triumeq'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'hiv'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review the combined dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:29:04
Query 'Per DM CLR: Please review the combined dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Dose was corrected.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:00:47
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:00:11
User entered '600/50/300' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 16:00:11
User opened query 'Per DM CLR: Please review the combined dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:18:25
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 09:35:08
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dose and dose unit has been updated.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:36
User entered '350/150/75' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 12:04:41
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 12:03:41
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 12:03:41

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '350mg/150mg/75mg' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 12:03:41
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	11 Feb 2021 09:56:54
' (Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	04 Jan 2021 16:34:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'I'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:04:41
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 12:04:41
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 12:04:41
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'tablet (TABLET)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'once daily (QD)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2010'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:19:54
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:19:54
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:19:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:19:54
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:19:54
User entered '6 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:19:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
User entered '1'	System	21 Oct 2020 17:19:28



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
User entered '1'	System	21 Oct 2020 17:19:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:10
User entered '804 (804)'	System	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: INDOLE DERIVATIVES, PRODUCT: LURASIDONE HYDROCHLORIDE, PRODUCTSYNONYM: LATUDA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:22:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:22:32
Data point term sent to Coder	System	21 Oct 2020 17:21:23
User entered 'latuda'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'bipolar disorder'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '40'	Junlin Long (b) (4)	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'once daily (QD)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2020'	Junlin Long (b) (4)	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:22
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:22
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:22
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:22
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:22
User entered '6 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:20:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
User entered '1'	System	21 Oct 2020 17:20:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
User entered '1'	System	21 Oct 2020 17:20:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:16
User entered '804 (804)'	System	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:08:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:08:08
Data point term sent to Coder	System	02 Mar 2021 16:22:14
Data point term sent to Coder	System	25 Feb 2021 14:09:43
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 14:09:15
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 07:16:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 07:16:24
Data point term sent to Coder	System	21 Oct 2020 17:21:23
User entered 'depakote'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'ANXIETY, SCHIZOPHRENIA, Seizures' reason for change: New Information	(b) (4)	02 Mar 2021 16:21:43
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 14:09:15
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 14:09:15
User entered 'ANXIETY, Schizophrenia' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:09:15
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'anxiety'	(b) (4)	21 Oct 2020 17:21:13
	Junlin Long (b) (4)	
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '500'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'twice daily (BID)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2000'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:53
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:53
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:53
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:20:53
User entered '6 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:13

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
User entered '2'	System	21 Oct 2020 17:21:13

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
User entered '1'	System	21 Oct 2020 17:21:13

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:23
User entered '804 (804)'	System	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:23:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:23:19
Data point term sent to Coder	System	21 Oct 2020 17:22:27
User entered 'seroquel'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:21:55



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'paranoia'	Junlin Long (b) (4)	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '400'	Junlin Long	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	Junlin Long	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'once daily (QD)'	Junlin Long	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	Junlin Long	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:21:55



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:53:31
Signature has been broken.	(b) (4), (b) (6)	22 Feb 2021 18:53:31
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 18:53:31
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2000'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:56:39
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 18:56:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4) Junlin Long (b) (4)	04 Jan 2021 16:21:15
Signature has been broken.	(b) (4) Junlin Long (b) (4)	04 Jan 2021 16:21:15
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	04 Jan 2021 16:21:15
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'End date is prior to start date. Please correct.' (Site from System). Signature has been broken.	(b) (4) System	22 Feb 2021 18:56:39
User entered empty; reason for change New Information	(b) (4), (b) (6)	22 Feb 2021 18:56:39
User opened query 'End date is prior to start date. Please correct.' (Site from System). User signature succeeded.	System Susanne Doblecki-Lewis	22 Feb 2021 18:53:31 14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4) Junlin Long (b) (4)	04 Jan 2021 16:21:15
Signature has been broken.	(b) (4) Junlin Long (b) (4)	04 Jan 2021 16:21:15
User entered '11 Nov 2020' reason for change: New Information	(b) (4) Junlin Long (b) (4)	04 Jan 2021 16:21:15
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4) Junlin Long (b) (4)	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:21:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:21:55



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:38:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:38:51
Data point term sent to Coder	System	25 Feb 2021 14:20:03
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 14:19:02
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:24:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:24:37
Data point term sent to Coder	System	21 Oct 2020 17:23:28
User entered 'montelukast'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:19:02
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 14:19:02
User entered 'ASTHMA, Chronic Obstructive Pulmonary Disease' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 14:19:02
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'asthma'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '10'	Junlin Long	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	Junlin Long	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'once daily (QD)'	Junlin Long	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:22:41



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	Junlin Long	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2000'	Junlin Long	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:22:41



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:22:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:25:44
Data point term sent to Coder	System	21 Oct 2020 17:24:31
User entered 'ibuprofen'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
User closed query 'Per DM CLR: Please note that there is no ongoing Right Ankle Pain recorded in MH eCRF during this timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:35:22
Query 'Per DM CLR: Please note that there is no ongoing Right Ankle Pain recorded in MH eCRF during this timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'MH has been updated.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:13:48
User opened query 'Per DM CLR: Please note that there is no ongoing Right Ankle Pain recorded in MH eCRF during this timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:00:15
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'right ankle pain'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '800'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '3 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:21:35
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:21:35
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:21:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:21:35
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:21:35
User entered '6 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
User entered empty.	System	21 Oct 2020 17:23:43

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
User entered empty.	System	21 Oct 2020 17:23:43

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:46
User entered empty.	System	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:25:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:25:45
Data point term sent to Coder User entered 'lyrica'	System Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:24:31 21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:24:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'nerve damage'	Junlin Long (b) (4)	21 Oct 2020 17:24:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '150'	Junlin Long	21 Oct 2020 17:24:28



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	Junlin Long	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'once daily (QD)'	Junlin Long	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:24:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	Junlin Long	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:24:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2010'	Junlin Long	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:24:28



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:24:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:24:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:24:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:26:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:26:36
Data point term sent to Coder	System	21 Oct 2020 17:25:34
User entered 'xarelto'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:25:24



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'prophylaxis for Deep vein thrombosis'	Junlin Long (b) (4)	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '10'	Junlin Long	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	Junlin Long	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'once daily (QD)'	Junlin Long	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:25:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	Junlin Long	21 Oct 2020 17:25:24

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:25:24



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:58:39
Signature has been broken.	(b) (4), (b) (6)	22 Feb 2021 18:58:39
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 18:58:39
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2017'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:25:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:25:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:25:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:25:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:25:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:25:24



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:27:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:27:41
Data point term sent to Coder	System	21 Oct 2020 17:26:37
User entered 'albuterol'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'asthma'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '90'	Junlin Long (b) (4)	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'ug (ug)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'other (OTHER)'	Junlin Long (b) (4)	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'every 4 to 6 hours as needed'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2015'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:22:20
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:22:20
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:22:20
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:22:20
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:22:20
User entered '6 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:26:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
User entered empty.	System	21 Oct 2020 17:26:26



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
User entered empty.	System	21 Oct 2020 17:26:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:40:56
User entered empty.	System	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 21:17:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:17:45
Data point term sent to Coder	System	21 Oct 2020 17:28:39
User entered 'duoneb (Ipratropium bromide/albuterol)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'asthma'	Junlin Long (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User closed query '	(b) (4)	05 Jan 2021 09:57:58
Per DM CLR: Please review the dose recorded (0.3) as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	
Query '	Junlin Long	04 Jan 2021 16:04:25
Per DM CLR: Please review the dose recorded (0.3) as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dose updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Junlin Long	04 Jan 2021 16:04:19
Signature has been broken.	(b) (4)	04 Jan 2021 16:04:19
User entered '0.5/3' reason for change: Per Query Resolution	Junlin Long	
User opened query '	(b) (4)	23 Dec 2020 04:02:45
Per DM CLR: Please review the dose recorded (0.3) as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0.5/0.3'	(b) (4)	21 Oct 2020 17:27:52
	Junlin Long	
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'other (OTHER)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'every 8 hours as needed'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un UNK 2015'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:23:22
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:23:22
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:23:22
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:23:22
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:23:22
User entered '6 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:27:52

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
User entered empty.	System	21 Oct 2020 17:27:52

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
User entered empty.	System	21 Oct 2020 17:27:52

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:19
User entered empty.	System	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 17:29:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:29:34
Data point term sent to Coder	System	21 Oct 2020 17:28:43
User entered 'tylenol'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User closed query ' Per DM CLR: Prophylaxis=YES. RIGHT ANKLE SURGERY is recorded as an actual medical condition in the Med Hx eCRF. Please review and update the response to NO. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:30:45
Query ' Per DM CLR: Prophylaxis=YES. RIGHT ANKLE SURGERY is recorded as an actual medical condition in the Med Hx eCRF. Please review and update the response to NO. Otherwise, clarify.'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:05:27
answered with 'updated' (Site from DM).		
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:05:21
Signature has been broken.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:05:21
User entered 'No (N)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:05:21
User opened query ' Per DM CLR: Prophylaxis=YES. RIGHT ANKLE SURGERY is recorded as an actual medical condition in the Med Hx eCRF. Please review and update the response to NO. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:19:20
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no ongoing Right Ankle Pain recorded in MH eCRF during this timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:35:36
Query 'Per DM CLR: Please note that there is no ongoing Right Ankle Pain recorded in MH eCRF during this timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'MH has been updated to reflect Right Ankle Pain.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 14:10:13
User opened query 'Per DM CLR: Please note that there is no ongoing Right Ankle Pain recorded in MH eCRF during this timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:01:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'right ankle pain'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:28:33

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '500'	Junlin Long	21 Oct 2020 17:28:33



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'mg (mg)'	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'as needed (PRN)'	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Oral (ORAL)'	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'un Oct 2020'	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	Junlin Long	21 Oct 2020 17:28:33



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	Junlin Long	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	Junlin Long	21 Oct 2020 17:28:33

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:28:33

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:28:33

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE, PRODUCTSYNONYM: NEOSPORIN [BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:51:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:51:33
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4)	04 Jan 2021 16:07:03 04 Jan 2021 16:06:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE, PRODUCTSYNONYM: NEOSPORIN [BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:09:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:09:08
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	10 Nov 2020 16:52:09
Data point term sent to Coder	System	05 Nov 2020 18:04:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'DM-Coding: Please add the active System ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).		05 Nov 2020 18:04:15
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'ingredient names updated' (Site from System).	Junlin Long (b) (4)	05 Nov 2020 18:04:15
Signature has been broken.	Junlin Long (b) (4)	05 Nov 2020 18:03:47
User entered 'NEOSPORIN (bacitracin, neomycin and polymyxin B)' reason for change: Per Query Resolution	Junlin Long (b) (4)	05 Nov 2020 18:03:47
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	26 Oct 2020 14:30:22
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
Data point term sent to Coder	System	21 Oct 2020 17:30:45
User entered 'neosporin'	Junlin Long (b) (4)	21 Oct 2020 17:30:05



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Prophylaxis=Yes. Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis as well as, this medication was given more than a month. Please update as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:28:12
Query 'Per DM CLR: Prophylaxis=Yes. Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis as well as, this medication was given more than a month. Please update as appropriate. Otherwise, clarify' answered with 'Date Entry Error. Corrected and updated.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:21:35
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 17:20:45
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 17:20:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 17:20:45
User opened query 'Per DM CLR: Prophylaxis=Yes. Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis as well as, this medication was given more than a month. Please update as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:13:50
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:29:31
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'New medical history has been added.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:02:42
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:02:31
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:25:37
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' answered with 'Participant did not have a right ankle infection at the time of screening. Only a recent surgery on 10/03/2020 was reported. In addition, this medication is not given to treat Anxiety. There should not be an AE of worsening Anxiety. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:30:50
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:08:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 11:44:58
User closed query 'Indication is listed as "right ankle pain", however medicine is an anti-bacterial. Consider an infective etiology.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:44:54
Query 'Indication is listed as "right ankle pain", however medicine is an anti-bacterial. Consider an infective etiology.' answered with 'updated' (Site from CRA).	Junlin Long (b) (4)	04 Jan 2021 16:06:23
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 16:06:16
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	04 Jan 2021 16:06:16
	(b) (4)	
User entered 'RIGHT ANKLE infection' reason for change: Per Query Resolution	Junlin Long (b) (4)	04 Jan 2021 16:06:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'Indication is listed as "right ankle pain", however medicine is an anti-bacterial. Consider an infective etiology.' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:54:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'right ankle pain'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Other (OTHER)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:10:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'application'	Junlin Long (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'Topical (TOPICAL)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '3 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:24:46
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:24:46
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:24:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:24:46
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:24:46
User entered '6 Nov 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:30:05

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
User entered empty.	System	21 Oct 2020 17:30:05



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
User entered empty.	System	21 Oct 2020 17:30:05

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:26
User entered empty.	System	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:58:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:58:51
Data point term sent to Coder	System	09 Dec 2020 19:21:23
User entered 'cefepime'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'right ankle cellulitis/sepsis/uti'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '2'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'g (g)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 12 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '9 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User entered empty.	System	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User entered empty.	System	09 Dec 2020 19:20:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:33
User entered empty.	System	09 Dec 2020 19:20:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
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) (b) (4)	11 Dec 2020 10:04:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:04:51
Data point term sent to Coder	System	09 Dec 2020 19:22:24
User entered 'vancomycin'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'right ankle cellulitis/sepsis/uti'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '1.25'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'g (g)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per CDM Query: Please review Frequency, as there is an option available for Twice Daily (instead of Other - every 12 hours). Thank you' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:35:39
Query 'Per CDM Query: Please review Frequency, as there is an option available for Twice Daily (instead of Other - every 12 hours). Thank you' answered with 'corrected frequency to reflect twice a day.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:07:35
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:07:09
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:07:09
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:07:09
User opened query 'Per CDM Query: Please review Frequency, as there is an option available for Twice Daily (instead of Other - every 12 hours). Thank you' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 21:47:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:07:09
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:07:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:07:09
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 12 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '8 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:22:09

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User entered '2'	System	07 Apr 2021 16:07:09
User entered empty.	System	09 Dec 2020 19:22:09

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User entered '1'	System	07 Apr 2021 16:07:09
User entered empty.	System	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:10:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:42
User entered '804 (804)'	System	07 Apr 2021 16:07:09
User entered empty.	System	09 Dec 2020 19:22:09

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:01:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:01:11
Data point term sent to Coder	System	26 Jan 2021 15:00:27
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:59:56
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:52:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:52:40
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 19:51:55
User entered 'narcant'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:00:16
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:00:03
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:59:56
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:59:56
User entered 'LETHARGY - suspected opioid abuse' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:59:56
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:49:54
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'lethargy'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'unknown'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'unknown'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'unknown'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:51:29

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User entered empty.	System	09 Dec 2020 19:51:29

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User entered empty.	System	09 Dec 2020 19:51:29

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:41:44
User entered empty.	System	09 Dec 2020 19:51:29



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:26:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:26:03
Data point term sent to Coder	System	26 Jan 2021 15:01:28
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:00:46
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 23:54:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 23:54:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 19:52:56
User entered 'ketorolac'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:01:44
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:00:52
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:00:46
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:00:46
User entered 'RIGHT LEG PAIN - cellulitis' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:00:46
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:50:31
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'right leg pain'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '30'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 6 hours as needed'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:25:32
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:25:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 19:52:42
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:25:32
User entered '10 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:25:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 19:52:42
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:52:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User entered empty.	System	09 Dec 2020 19:52:42



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User entered empty.	System	09 Dec 2020 19:52:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:14
User entered empty.	System	09 Dec 2020 19:52:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 22:22:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:22:50
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 19:54:58
User entered 'insulin lispro (humalog)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'diabetes'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '1-5'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'unit'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 6 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Subcutaneous (SUBCUTANEOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54



US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:54:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 19:54:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 19:54:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 19:54:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 19:57:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 19:57:03
Data point term sent to Coder	System	09 Dec 2020 19:56:00
User entered 'alprazolam'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User closed query 'Per CDM: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 08:49:12
Query 'Per CDM: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded and update con med indication or provide clarification.' answered with 'Prior to first hospital admission, participant was taking medication for anxiety. Depakote was stopped upon admission and she was started on Alprazolam. We do not consider this to be worsening anxiety.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:33:07
User opened query 'Per CDM: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:38:25
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'anxiety'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'l'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'as needed (PRN)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:35:45
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' answered with 'Participant did not have a right ankle infection at the time of screening. Only a recent right ankle surgery on 10/03/2020 was reported. In addition, this medication is not given to treat anxiety. There should not be an AE of Worsening Anxiety. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:33:01
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:15:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:27:49
User entered '10 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:27:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '11 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 19:55:48
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:55:48

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User entered empty.	System	09 Dec 2020 19:55:48

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User entered empty.	System	09 Dec 2020 19:55:48

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:40
User entered empty.	System	09 Dec 2020 19:55:48

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 22:33:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:33:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 19:58:05
User entered 'iohexol 30000 mg iv injection'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'iv contrast (right leg ct scan)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '100'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mL (mL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once (ONCE)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:57:16

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User entered empty.	System	09 Dec 2020 19:57:16

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User entered empty.	System	09 Dec 2020 19:57:16

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:46
User entered empty.	System	09 Dec 2020 19:57:16



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:22:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:22:58
Data point term sent to Coder	System	26 Jan 2021 15:02:29
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:01:50
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 10:12:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 10:12:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 19:59:14
User entered 'Pantoprazole'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 15:01:50
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 15:01:50
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 15:01:50
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4)	09 Dec 2020 19:58:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:02:46
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:01:55
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:01:50
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:01:50
User entered 'prophylaxis for GASTROINTESTINAL (GI) BLEED' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:01:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:51:24
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Gastrointestinal (GI) bleeding'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '20'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'twice daily (BID)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:28:33
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:28:33
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 19:58:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:28:33
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:28:33
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 19:58:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:10:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User entered '2'	System	09 Dec 2020 19:58:33



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User entered '1'	System	09 Dec 2020 19:58:33

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:49
User entered '804 (804)'	System	09 Dec 2020 19:58:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User closed query 'Per DM CLR: Con Med BUDESONIDE was added on 6 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:04:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDs, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:10:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:10:00
Data point term sent to Coder	System	26 Jan 2021 15:03:30
Query 'Per DM CLR: Con Med BUDESONIDE was added on 6 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' answered with 'indication updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:03:21
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:03:14
User opened query 'Per DM CLR: Con Med BUDESONIDE was added on 6 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:43:48
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 20:02:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 20:02:04
Data point term sent to Coder	System	09 Dec 2020 20:01:15
User entered 'budesonide'	Junlin Long (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 15:03:14
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 15:03:14
User entered 'ASTHMA/intermittent wheezing'	(b) (4)	
reason for change: Per Query Resolution	Junlin Long (b) (4)	26 Jan 2021 15:03:14
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'asthma'	(b) (4)	
	Junlin Long (b) (4)	09 Dec 2020 20:00:26
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0.25'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'twice daily (BID)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:07:04
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' answered with 'According to medical records, participant was taking Budesonide (Pulmicort) at home prior to admission. Participant failed to report this medication at screening visit. ConMed has been added and will update once more information is obtained. Therefore, this medication was not given because of worsening Asthma. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:22:31
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:30:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:29:31
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:29:31
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:00:26
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:29:31
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:29:31
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:00:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:00:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User entered '2'	System	09 Dec 2020 20:00:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User entered '1'	System	09 Dec 2020 20:00:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:54
User entered '804 (804)'	System	09 Dec 2020 20:00:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
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) (b) (4)	09 Dec 2020 20:33:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:33:00
Data point term sent to Coder	System	09 Dec 2020 20:31:59
Coding entries removed.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:31:26
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) (b) (4)	09 Dec 2020 20:03:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:03:07
Data point term sent to Coder	System	09 Dec 2020 20:02:17
User entered 'acetaminophen'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:31:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:31:26
User entered 'pain right ankle' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:31:26
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:01:21
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Please provide the specific dose for this medication instead of recording the dose range. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:05:46
Query 'Per DM CLR: Please provide the specific dose for this medication instead of recording the dose range. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:04:51
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:04:38
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:04:38
User entered '500' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:04:38
User opened query 'Per DM CLR: Please provide the specific dose for this medication instead of recording the dose range. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:52:08
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '500-1000'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 4 hours as needed'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '06 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:29:56
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:29:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:01:21
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:29:56
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:29:56
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:01:21
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:01:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User entered empty.	System	09 Dec 2020 20:01:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User entered empty.	System	09 Dec 2020 20:01:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:42:59
User entered empty.	System	09 Dec 2020 20:01:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 17:03:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:03:28
Data point term sent to Coder	System	04 Jan 2021 16:08:03
Coding entries removed.	Junlin Long (b) (4)	04 Jan 2021 16:07:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:14:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:14:49
Data point term sent to Coder	System	10 Dec 2020 18:15:04
Data point term sent to Coder	System	09 Dec 2020 20:03:20
User entered 'clindamycin'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 11:46:02
User closed query 'Consider removing the drug class from the indication.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:45:57
Query 'Consider removing the drug class from the indication.' answered with 'updated' (Site from CRA).	Junlin Long (b) (4)	04 Jan 2021 16:07:19
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:07:08
User entered 'RIGHT ANKLE CELLULITIS/SEPSIS' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:07:08
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'Consider removing the drug class from the indication.' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:56:24
User entered 'ANTIBIOTIC right ankle cellulitis/sepsis' reason for change: Data Entry Error	Junlin Long (b) (4)	10 Dec 2020 18:14:54
User entered 'antibiotics right ankle'	(b) (4)	
	Junlin Long (b) (4)	09 Dec 2020 20:02:28
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '600'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once (ONCE)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:02:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User entered empty.	System	09 Dec 2020 20:02:28

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User entered empty.	System	09 Dec 2020 20:02:28



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:04
User entered empty.	System	09 Dec 2020 20:02:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
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.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 16:34:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:34:28
Data point term sent to Coder	System	04 Jan 2021 16:08:05
Coding entries removed.	Junlin Long (b) (4)	04 Jan 2021 16:07:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
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) (b) (4)	11 Dec 2020 10:03:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:03:47
Data point term sent to Coder	System	10 Dec 2020 18:15:06
Data point term sent to Coder	System	09 Dec 2020 20:03:23
User entered 'vancomycin'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 11:46:19
User closed query 'consider removing the drug class from the indication.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:46:14
Query 'consider removing the drug class from the indication.' answered with 'updated' (Site from CRA).	Junlin Long (b) (4)	04 Jan 2021 16:07:44
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:07:40
User entered 'RIGHT ANKLE CELLULITIS/SEPSIS' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:07:40
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'consider removing the drug class from the indication.' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:56:53
User entered 'ANTIBIOTIC right ankle cellulitis/sepsis' reason for change: Data Entry Error	Junlin Long (b) (4)	10 Dec 2020 18:15:04
User entered 'antibiotic right ankle'	(b) (4)	
	Junlin Long (b) (4)	09 Dec 2020 20:03:20
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'l'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'g (g)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
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).	(b) (4)	
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	04 Jan 2021 16:31:08
DataPoint Un-verified.	System	04 Jan 2021 16:31:08
User entered 'twice daily (BID)' reason for change: New Information	Junlin Long (b) (4)	04 Jan 2021 16:31:08
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).	Junlin Long (b) (4)	04 Jan 2021 16:31:08
DataPoint Verified.	(b) (4)	
User entered 'once (ONCE)'	System	04 Jan 2021 16:30:48
	(b) (4), (b) (6)	15 Dec 2020 13:07:28
	Junlin Long (b) (4)	09 Dec 2020 20:03:20
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '8 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:30:48
User entered '11 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:30:48
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '8 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:03:20
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:03:20



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User entered '2'	System	04 Jan 2021 16:31:08
User entered empty.	System	09 Dec 2020 20:03:20

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User entered '1'	System	04 Jan 2021 16:31:08
User entered empty.	System	09 Dec 2020 20:03:20

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:10
User entered '804 (804)'	System	04 Jan 2021 16:31:08
User entered empty.	System	09 Dec 2020 20:03:20

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
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.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:05:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:05:58
Data point term sent to Coder	System	09 Dec 2020 20:05:24
User entered 'nicotine patch'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'mh updated' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:07:26
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	Junlin Long (b) (4)	26 Jan 2021 15:06:00
User signature succeeded.	(b) (4)	
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:54:00
DataPoint Verified.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'smoking cessation'	Junlin Long (b) (4)	09 Dec 2020 20:05:17
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '21'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Transdermal (TRANSDERMAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '10 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:31:32
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:31:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:05:17
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:31:32
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:31:32
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:05:17
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:05:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User entered '1'	System	09 Dec 2020 20:05:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User entered '1'	System	09 Dec 2020 20:05:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:14
User entered '804 (804)'	System	09 Dec 2020 20:05:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:07:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:07:07
Data point term sent to Coder	System	26 Jan 2021 15:06:37
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:26
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:08:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:08:02
Data point term sent to Coder	System	09 Dec 2020 20:07:25
User entered 'lactated ringers'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:09:48
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:30
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:26
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:26
User entered 'BLOOD PRESSURE SUPPORT - hypotension' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:26
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:55:13
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'blood pressure support'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '125'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mL (mL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'per hour continuous'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:23:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'AE start date was correct. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 19:15:57
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:14:05
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:50
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 19:12:50
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:12:50
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:56:48
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '10 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:06:44

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User entered empty.	System	09 Dec 2020 20:06:44

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User entered empty.	System	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:10:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:19
User entered empty.	System	09 Dec 2020 20:06:44

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:08:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:08:09
Data point term sent to Coder	System	26 Jan 2021 15:07:37
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:52
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:16:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:16:53
Data point term sent to Coder	System	10 Dec 2020 18:16:07
Coding entries removed.	Junlin Long (b) (4) (b) (4)	10 Dec 2020 18:15:46



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 20:10:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 20:10:59
Data point term sent to Coder	System	09 Dec 2020 20:10:27
User entered 'Piperacillin/Tazobactam'	Junlin Long (b) (4)	09 Dec 2020 20:10:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:13:18
Query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:56
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:52
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:52
User entered 'RIGHT ANKLE CELLULITIS/SEPSIS' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:06:52
User opened query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:56:23
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'ANTIBIOTIC right ankle cellulitis/sepsis' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	10 Dec 2020 18:15:46
User entered 'antibiotic'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '3.375'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'g (g)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 6 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:32:30
User entered '12 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:32:30
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '10 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:10:19
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:32:16
User entered '12 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:32:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '11 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:10:19
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:10:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User entered empty.	System	09 Dec 2020 20:10:19



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User entered empty.	System	09 Dec 2020 20:10:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:23
User entered empty.	System	09 Dec 2020 20:10:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
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) (b) (4)	26 Jan 2021 15:08:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:08:09
Data point term sent to Coder	System	26 Jan 2021 15:07:39
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
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) (b) (4)	11 Dec 2020 10:03:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:03:48
Data point term sent to Coder	System	10 Dec 2020 18:16:07
Data point term sent to Coder	System	09 Dec 2020 20:11:28
User entered 'vancomycin'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:13:44
Query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:07:09
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:07:04
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:07:04
User entered 'RIGHT ANKLE CELLULITIS/SEPSIS' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:07:04
User opened query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:57:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'ANTIBIOTIC right ankle cellulitis/sepsis' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	10 Dec 2020 18:15:56
User entered 'antibiotic right ankle'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '750'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	09 Dec 2020 20:12:28
User entered 'other (OTHER)' reason for change:	Junlin Long (b) (4)	09 Dec 2020 20:12:28
Data Entry Error	(b) (4)	
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	09 Dec 2020 20:11:15
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 12 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:33:06
User entered '15 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:33:06
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '11 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:11:15
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:11:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User entered empty.	System	09 Dec 2020 20:12:28
User entered '1'	System	09 Dec 2020 20:11:15

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User entered empty.	System	09 Dec 2020 20:12:28
User entered '1'	System	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:10:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:27
User entered empty.	System	09 Dec 2020 20:12:28
User entered '804 (804)'	System	09 Dec 2020 20:11:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:48:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:48:40
User closed query 'Per DM CLR: Please review and remove the extraneous information (i.e. 2.5MG/0.5MG) from the medication name field as this is already recorded in the Dose and Units field. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:36:04
Query 'Per DM CLR: Please review and remove the extraneous information (i.e. 2.5MG/0.5MG) from the medication name field as this is already recorded in the Dose and Units field. Update eCRF as appropriate.' answered with 'Corrections made.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:09:01
Data point term sent to Coder	System	07 Apr 2021 16:08:55
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 16:08:18
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:08:18
User entered 'IPRATROPIUM BROMIDE/ALBUTEROL' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:08:18
User opened query 'Per DM CLR: Please review and remove the extraneous information (i.e. 2.5MG/0.5MG) from the medication name field as this is already recorded in the Dose and Units field. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:08:45

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM BROMIDE/ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 12:08:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 12:08:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 22:02:44
Data point term sent to Coder	System	26 Feb 2021 16:55:18
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 16:55:08
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 16:55:08
User entered 'IPRATROPIUM BROMIDE/ALBUTEROL (2.5mg/0.5mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 16:55:08
Data point term sent to Coder	System	26 Feb 2021 16:49:10
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 16:48:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM BROMIDE/ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Jan 2021 13:30:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Jan 2021 13:30:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med IPRATROPIUM BROMIDE/ALBUTEROL was added on 11 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:14:43
Query 'Per DM CLR: Con Med IPRATROPIUM BROMIDE/ALBUTEROL was added on 11 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' answered with 'indication updated' (Site from DM).	Junlin Long (b) (4)	26 Jan 2021 15:07:46
Data point term sent to Coder	System	26 Jan 2021 15:07:39
Coding entries removed.	Junlin Long (b) (4)	26 Jan 2021 15:07:37
User opened query 'Per DM CLR: Con Med IPRATROPIUM BROMIDE/ALBUTEROL was added on 11 NOV 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	21 Jan 2021 14:45:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL - version WHODrug-Global-B3\202003.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	
DataPoint Verified.	Coder Import (b) (4)	17 Dec 2020 22:35:53
Data point term sent to Coder	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 13:07:28
	System	09 Dec 2020 20:12:28

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
User entered 'Ipratropium bromide/albuterol'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'ASTHMA - INTERMITTENT WHEEZING, ATELECTASIS' reason for change: New Information	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:55:08
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 16:48:20
User entered 'ASTHMA - INTERMITTENT WHEEZING Atelectasis' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 16:48:20
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
DataPoint Un-verified.	(b) (4) Junlin Long (b) (4)	26 Jan 2021 15:07:37
Signature has been broken.	(b) (4) Junlin Long (b) (4)	26 Jan 2021 15:07:37
User entered 'ASTHMA - intermittent wheezing' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	26 Jan 2021 15:07:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'asthma'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:32:18
Query 'Per DM CLR: Please provide the actual dose for this medication instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dose and Dose unit has been updated. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:00:41
User entered '2.5/0.5' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 16:58:38
User entered '3' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 16:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 16:53:27
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 16:53:27
User entered '2.5/0.5' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 16:53:27
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:38:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '3'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 16:58:38
User entered 'mL (mL)' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 16:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 16:53:27
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 16:53:27
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 16:53:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mL (mL)'	Junlin Long (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 6 hours as needed'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 05:36:39
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' answered with 'This medication was used to treat Asthma and Atelectasis and do not consider it to be worsening Asthma.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:03:08
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ASTHMA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:48:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:33:47
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:33:47
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:12:17
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:33:47
User entered '24 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:33:47
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:12:17
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:12:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User entered empty.	System	09 Dec 2020 20:12:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User entered empty.	System	09 Dec 2020 20:12:17



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:32
User entered empty.	System	09 Dec 2020 20:12:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN;SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:43:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:43:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN SODIUM;SULBACTAM SODIUM, PRODUCTSYNONYM: AMPICILLIN/SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:09:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:09:10
Data point term sent to Coder	System	26 Jan 2021 15:08:40
Coding entries removed.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:08:19
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN SODIUM;SULBACTAM SODIUM, PRODUCTSYNONYM: AMPICILLIN/SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:17:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:17:54
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	10 Dec 2020 18:17:10 10 Dec 2020 18:16:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN SODIUM;SULBACTAM SODIUM, PRODUCTSYNONYM: AMPICILLIN/SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:15:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:15:01
Data point term sent to Coder User entered 'ampicillin/sulbactam'	System Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:14:29 09 Dec 2020 20:13:49

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User closed query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:15:53
Query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:08:25
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:08:19
Signature has been broken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:08:19
User entered 'RIGHT ANKLE CELLULITIS/SEPSIS' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:08:19
User opened query 'Per DM CLR: Note, only diagnosis/medical condition are recorded on this field. Kindly remove the extraneous information (i.e. ANTIBIOTIC). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 15:00:16
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'ANTIBIOTIC right ankle cellulitis/sepsis' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	10 Dec 2020 18:16:13
User entered 'antibiotic right ankle'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '3'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'g (g)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 6 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:34:08
User entered '13 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:34:08
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '15 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:13:49
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:13:49

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User entered empty.	System	09 Dec 2020 20:13:49

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User entered empty.	System	09 Dec 2020 20:13:49

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:37
User entered empty.	System	09 Dec 2020 20:13:49

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ABACAVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:16:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:16:57
Data point term sent to Coder	System	09 Dec 2020 20:15:30
User entered 'abacavir'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'hiv'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '600'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '13 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '17 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:15:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User entered '1'	System	09 Dec 2020 20:15:24

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User entered '1'	System	09 Dec 2020 20:15:24

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:42
User entered '804 (804)'	System	09 Dec 2020 20:15:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: LAMIVUDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 00:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:24:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 20:16:33
User entered 'lamivudine'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'hiv'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '300'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '13 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '17 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:16:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User entered '1'	System	09 Dec 2020 20:16:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User entered '1'	System	09 Dec 2020 20:16:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:46
User entered '804 (804)'	System	09 Dec 2020 20:16:15



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: OTHER ANTIVIRALS, PRODUCT: DOLUTEGRAVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:18:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 20:18:56
Data point term sent to Coder	System	09 Dec 2020 20:17:34
User entered 'dolutegravir'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'hiv'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '50'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '13 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '17 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User entered '1'	System	09 Dec 2020 20:17:03



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User entered '1'	System	09 Dec 2020 20:17:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:55
User entered '804 (804)'	System	09 Dec 2020 20:17:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: TRIMETHOPRIM SULFAMETHOXAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 16:31:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:31:36
Data point term sent to Coder	System	04 Jan 2021 16:09:06
Coding entries removed.	Junlin Long (b) (4)	04 Jan 2021 16:08:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 11:45:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 11:45:53
Data point term sent to Coder	System	09 Dec 2020 20:19:38
User entered 'Trimethoprim/Sulfamethoxazole'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 11:47:09
User closed query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:47:00
Query 'Consider removing the drug class from the indication' answered with 'updated' (Site from CRA).	Junlin Long (b) (4)	04 Jan 2021 16:08:35
User entered 'prophylaxis for PCP' reason for change: Per Query Resolution	(b) (4)	04 Jan 2021 16:08:31
DataPoint Un-verified.	Junlin Long (b) (4)	04 Jan 2021 16:08:12
User entered 'PCP' reason for change: Per Query Resolution	(b) (4)	04 Jan 2021 16:08:12
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:58:11
User entered 'antibiotic - pcpr'	Junlin Long (b) (4)	09 Dec 2020 20:18:38
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '160/800'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '13 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:36:00
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:36:00
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:18:38
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:36:00
User entered '17 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:36:00
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:18:38
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:18:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User entered '1'	System	09 Dec 2020 20:18:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User entered '1'	System	09 Dec 2020 20:18:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:59
User entered '804 (804)'	System	09 Dec 2020 20:18:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMPICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 10:13:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 10:13:41
Data point term sent to Coder	System	04 Jan 2021 16:09:06
Coding entries removed.	Junlin Long (b) (4)	04 Jan 2021 16:08:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMPICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:45:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:45:54
Data point term sent to Coder	System	10 Dec 2020 18:17:10
Data point term sent to Coder	System	09 Dec 2020 20:19:39
User entered 'ampicillin'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 11:47:22
User closed query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:47:17
Query 'Consider removing the drug class from the indication' answered with 'updated' (Site from CRA).	Junlin Long (b) (4)	04 Jan 2021 16:08:50
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:08:46
User entered 'RIGHT ANKLE CELLULITIS/SEPSIS' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:08:46
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:58:43
User entered 'ANTIBIOTIC right ankle cellulitis/sepsis' reason for change: Data Entry Error	Junlin Long (b) (4)	10 Dec 2020 18:16:51
User entered 'antibiotic right ankle'	(b) (4)	
	Junlin Long (b) (4)	09 Dec 2020 20:19:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '2'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'g (g)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 4 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:36:27
User entered '14 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:36:27
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '16 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:19:26
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:36:27
User entered '16 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:36:27
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '17 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:19:26
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:19:26

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User entered empty.	System	09 Dec 2020 20:19:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User entered empty.	System	09 Dec 2020 20:19:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:03
User entered empty.	System	09 Dec 2020 20:19:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: HALOPERIDOL, PRODUCTSYNONYM: HALDOL [HALOPERIDOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 12:11:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 12:11:59
Data point term sent to Coder	System	26 Feb 2021 17:39:23
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 17:39:06
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: HALOPERIDOL, PRODUCTSYNONYM: HALDOL [HALOPERIDOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:09:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:09:41
Data point term sent to Coder	System	04 Jan 2021 16:09:08
Coding entries removed.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:08:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: HALOPERIDOL, PRODUCTSYNONYM: HALDOL [HALOPERIDOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:55:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:55:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28

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EAB) (1725)

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US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	09 Dec 2020 20:21:45
User entered 'haldol'	Junlin Long (b) (4)	09 Dec 2020 20:20:59
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query ' Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:26:26
Query ' Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'ConMed was updated to match the appropriate AE.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:40:09
DataPoint Un-verified.	(b) (4), (b) (6)	26 Feb 2021 17:39:06
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 17:39:06
User entered 'EPISODES OF AGITATION' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Feb 2021 17:39:06
User opened query ' Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:59:33
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:17:12
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'ae updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 15:12:45

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	21 Jan 2021 12:34:33
DataPoint Verified.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 11:56:48
User closed query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:47:34
Query 'Consider removing the drug class from the indication' answered with 'updated' (Site from CRA).	Junlin Long	(b) (4)
DataPoint Un-verified.	(b) (4)	04 Jan 2021 16:09:03
	Junlin Long	(b) (4)
	(b) (4)	04 Jan 2021 16:08:59
User entered 'AGITATION' reason for change: Per Query Resolution	Junlin Long	(b) (4)
DataPoint Verified.	(b) (4)	04 Jan 2021 16:08:59
	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:59:44
Query 'Consider removing the drug class from the indication' canceled (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:59:20
User opened query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 11:59:11
User entered 'antipsychotic - agitation'	Junlin Long	(b) (4)
	(b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '5'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:37:34
User entered 'as needed (PRN)' reason for change:	(b) (4)	
New Information	Junlin Long (b) (4)	04 Jan 2021 16:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'once (ONCE)'	Junlin Long (b) (4)	09 Dec 2020 20:20:59
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intramuscular (INTRAMUSCULAR)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:37:34
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 16:37:34
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4)	09 Dec 2020 20:20:59
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:20:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User entered empty.	System	09 Dec 2020 20:20:59



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User entered empty.	System	09 Dec 2020 20:20:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:06
User entered empty.	System	09 Dec 2020 20:20:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: MICONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:34:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:34:28
Data point term sent to Coder	System	04 Jan 2021 16:10:09
Coding entries removed.	Junlin Long (b) (4)	04 Jan 2021 16:09:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: MICONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:57:45
Data point term sent to Coder	System	09 Dec 2020 20:23:46
User entered 'miconazole 2% powder'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 11:57:02
User closed query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:56:58
Query 'Consider removing the drug class from the indication' answered with 'updated' (Site from CRA).	Junlin Long (b) (4)	04 Jan 2021 16:09:27
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:09:23
	(b) (4)	
User entered 'BILATERAL INGUINAL AREAS AND PANNUS FOLD' reason for change: Per Query Resolution	Junlin Long (b) (4)	04 Jan 2021 16:09:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'Consider removing the drug class from the indication' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 12:00:11
User entered 'antifungal powder bilateral inguinal areas and pannus fold'	Junlin Long (b) (4)	09 Dec 2020 20:23:21
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'I'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'application'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'twice daily (BID)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Topical (TOPICAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:23:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Dec 2020 20:23:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 20:23:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Dec 2020 20:23:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: DERMATOLOGICALS, ATC: MEDICATED DRESSINGS, ATC: MEDICATED DRESSINGS, PRODUCT: CALCIUM ALGINATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 14:27:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 14:27:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 20:24:47
User entered 'medihoney calcium alginate dressing'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'right ankle wound care'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'l'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'application'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every other day (QOD)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Topical (TOPICAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:38:17
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:38:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:24:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:38:17
User entered '24 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:38:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:24:41
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:24:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User entered '1'	System	09 Dec 2020 20:24:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User entered '2'	System	09 Dec 2020 20:24:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:41
User entered '804 (804)'	System	09 Dec 2020 20:24:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: DERMATOLOGICALS, ATC: MEDICATED DRESSINGS, ATC: MEDICATED DRESSINGS, ATC: ZINC BANDAGES, PRODUCT: ZINC OXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Dec 2020 02:24:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 02:24:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 20:26:50
User entered 'triad hydrophilic paste'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'intergluteal fold fissure wound care'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'I'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'application'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Topical (TOPICAL)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:26:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 20:26:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 20:26:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 20:26:04



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: FATTY ACID DERIVATIVES, PRODUCT: VALPROATE SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 16:35:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:35:31
Data point term sent to Coder	System	04 Jan 2021 16:10:09
Coding entries removed.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:10:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: FATTY ACID DERIVATIVES, PRODUCT: VALPROATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:06:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:06:55
Data point term sent to Coder	System	09 Dec 2020 20:27:53
User entered 'valproate sodium'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 11:58:00
User closed query 'Is this "Seizures"?' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 11:57:57
Query 'Is this "Seizures"?' answered with 'updated' (Site from CRA).	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:10:38
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:10:01
User entered 'Seizures' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:10:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User opened query 'Is this "Seizures"?' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 12:01:33
User entered 'serzures'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '250'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 6 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEIZURES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:09:15
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEIZURES should be recorded, and update con med indication or provide clarification. ' answered with 'According to medical records, participant has a history of seizures and has been on Depakote since 2000 but was stopped upon admission date. This is not considered a Worsening Seizures AE. Indication for Depakote in ConMed has been updated. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:36:23
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEIZURES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:02:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:38:51
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:38:51
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:27:17
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:38:51
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:38:51
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:27:17
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:27:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User entered empty.	System	09 Dec 2020 20:27:17



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User entered empty.	System	09 Dec 2020 20:27:17

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:16
User entered empty.	System	09 Dec 2020 20:27:17

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:08:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:08:05
Data point term sent to Coder	System	09 Dec 2020 20:28:53
User entered 'enoxaparin'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Deep Vein Thrombosis prophylaxis'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '40'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 12 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Subcutaneous (SUBCUTANEOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:39:17
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:39:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:28:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:39:17
User entered '25 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:39:17
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:28:41
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:28:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User entered empty.	System	09 Dec 2020 20:28:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User entered empty.	System	09 Dec 2020 20:28:41

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:21
User entered empty.	System	09 Dec 2020 20:28:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 09:12:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 09:12:38
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 16:14:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 16:14:35
Data point term sent to Coder	System	07 Apr 2021 16:10:56
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 16:10:50
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:58:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:58:31
Data point term sent to Coder	System	02 Mar 2021 16:48:52
Data point term sent to Coder	System	02 Mar 2021 16:47:50
Data point term sent to Coder	System	02 Mar 2021 16:39:35
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 16:39:18
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:48:44
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:15:11 04 Jan 2021 16:14:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:42:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:42:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	15 Dec 2020 13:07:28
Data point term sent to Coder	System	09 Dec 2020 20:30:58
User entered 'potassium chloride'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User closed query 'Per CDM: Indication is recorded as "SUPPLEMENT", as supplements/vitamins/contraceptives and vaccines are considered as 'prophylaxis'. Please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 03:16:31
Query 'Per CDM: Indication is recorded as "SUPPLEMENT", as supplements/vitamins/contraceptives and vaccines are considered as 'prophylaxis'. Please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' answered with 'indication updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:14:32
User opened query 'Per CDM: Indication is recorded as "SUPPLEMENT", as supplements/vitamins/contraceptives and vaccines are considered as 'prophylaxis'. Please verify if field 'Prophylaxis' should be updated to 'Yes', else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:30:04
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review the indication of this CM as this is not the usual use for this CM. Note, this CM is used to treat HYPOKALEMIA, not for HYPOCALCEMIA. Either change the indication or provide explanation for alternate/different use. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:40:53
Query 'Per DM CLR: Please review the indication of this CM as this is not the usual use for this CM. Note, this CM is used to treat HYPOKALEMIA, not for HYPOCALCEMIA. Either change the indication or provide explanation for alternate/different use. ' answered with 'Indication was corrected. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:11:14
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:10:50
User entered 'HYPOKALEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:10:50
User opened query 'Per DM CLR: Please review the indication of this CM as this is not the usual use for this CM. Note, this CM is used to treat HYPOKALEMIA, not for HYPOCALCEMIA. Either change the indication or provide explanation for alternate/different use. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:04:52
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 03:13:35
User entered 'HYPOKALCEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:48:26



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.  ' answered with 'Medication Indication, and ConMed has been updated. New AE has been entered.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:47:33
User entered 'hypocalcemia' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:47:23
Signature has been broken.	(b) (4), (b) (6)	02 Mar 2021 16:39:18
User entered 'potassium REPLACEMENT' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:39:18
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:02:34
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long	(b) (4)
User entered 'electrolyte replacement' reason for change: Per Query Resolution	(b) (4)	04 Jan 2021 16:14:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'supplement'	Junlin Long	(b) (4)
	(b) (4)	09 Dec 2020 20:30:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '10'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'meq'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'other (OTHER)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'every 2 hours'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '18 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered '0'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:39:37
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:39:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Dec 2020 20:30:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:39:37
User entered '19 Nov 2020' reason for change: New Information	(b) (4)	04 Jan 2021 16:39:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered empty.	Junlin Long (b) (4)	09 Dec 2020 20:30:02
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:28
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 20:30:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User entered empty.	System	09 Dec 2020 20:30:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User entered empty.	System	09 Dec 2020 20:30:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:10:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:32
User entered empty.	System	09 Dec 2020 20:30:02



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:31
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:36:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:36:32
Data point term sent to Coder	System	04 Jan 2021 16:42:42
User entered 'normal saline IV'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hypotension'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '1-2'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'liter'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'as ordered for significant hypotension'	Junlin Long (b) (4)	04 Jan 2021 16:42:15



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:42:15
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '10 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '13 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:42:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
User entered empty.	System	04 Jan 2021 16:42:15



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
User entered empty.	System	04 Jan 2021 16:42:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:47
User entered empty.	System	04 Jan 2021 16:42:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 18:38:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:38:33
Data point term sent to Coder	System	04 Jan 2021 16:45:44
User entered 'lactated ringers IV'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hypotension'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'liter'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'as ordered for significant hypotension'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Junlin Long (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:44:57
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '10 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '11 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:44:57



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:44:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
User entered empty.	System	04 Jan 2021 16:44:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
User entered empty.	System	04 Jan 2021 16:44:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:51
User entered empty.	System	04 Jan 2021 16:44:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:51:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:51:36
Data point term sent to Coder	System	07 Apr 2021 15:48:13
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 15:47:36
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
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: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:39:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:39:29
Data point term sent to Coder	System	04 Jan 2021 16:47:45
User entered 'calcium gluconate'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 15:47:36
User entered 'Hypocalcemia (2nd Episode)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:47:36
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.'	(b) (4), (b) (6)	01 Mar 2021 05:21:47
(Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.'	(b) (4), (b) (6)	26 Feb 2021 19:05:34
answered with 'AE added to reflect indication of this medication.'		
(Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.'	(b) (4), (b) (6)	11 Feb 2021 11:02:58
(Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'calcium replacement'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:47:03
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once (ONCE)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:47:03
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:47:03

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:47:03
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '12 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 16:47:03



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '12 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:47:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
User entered empty.	System	04 Jan 2021 16:47:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
User entered empty.	System	04 Jan 2021 16:47:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:45:57
User entered empty.	System	04 Jan 2021 16:47:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:41
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:51:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:51:44
Data point term sent to Coder	System	02 Mar 2021 17:51:06
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 17:51:00
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:44
Data point term sent to Coder	System	04 Jan 2021 16:48:45
User entered 'magnesium sulfate'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 03:15:48
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	02 Mar 2021 17:51:48
' answered with 'New AE has been opened matching ConMed indication.' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	02 Mar 2021 17:51:00
User entered 'Hypomagnesemia' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 17:51:00
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 11:03:28
' (Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'magnesium replacement'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:48:07
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once (ONCE)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:48:07
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:48:07

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:48:07
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '12 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 16:48:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '12 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:48:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:48:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
User entered empty.	System	04 Jan 2021 16:48:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
User entered empty.	System	04 Jan 2021 16:48:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:03
User entered empty.	System	04 Jan 2021 16:48:07



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
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: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 10:09:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 10:09:41
Data point term sent to Coder	System	04 Jan 2021 16:52:47
User entered 'acyclovir'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:11:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 19:11:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 09:16:48
Query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'This medication was given prophylactically for potential CNS infection as they suspected Meningitis. It was not given for sepsis. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:11:33
User opened query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:03:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'potential CNS infection'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '550'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:51:47
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 8 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:51:47
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '14 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 16:51:47

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:51:47

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
User entered empty.	System	04 Jan 2021 16:51:47



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
User entered empty.	System	04 Jan 2021 16:51:47

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:08
User entered empty.	System	04 Jan 2021 16:51:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 16:39:30
	(b) (4)	
Data point term sent to Coder	System	04 Jan 2021 16:53:47
User entered 'cefepime'	Junlin Long (b) (4)	04 Jan 2021 16:52:54
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:13:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 19:13:03
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 09:17:12
Query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'This medication was given prophylactically for potential CNS infection as they suspected Meningitis. It was not given for sepsis. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:12:57
User opened query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:04:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'potential CNS infection'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '2'	Junlin Long (b) (4)	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:52:54
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 8 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:52:54

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:52:54
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '14 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:52:54



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
User entered empty.	System	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
User entered empty.	System	04 Jan 2021 16:52:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:25
User entered empty.	System	04 Jan 2021 16:52:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 15:18:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:18:44
Data point term sent to Coder	System	04 Jan 2021 16:53:49
User entered 'vancomycin'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:13:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 19:13:54
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 09:18:31
Query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'This medication was given prophylactically for potential CNS infection as they suspected Meningitis. It was not given for sepsis. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:13:48
User opened query 'Per DM CLR: Please note, there is a medical condition if SEPSIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:05:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'potential CNS infection'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:53:46
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 12 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:53:46

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:53:46
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '15 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:53:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
User entered empty.	System	04 Jan 2021 16:53:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
User entered empty.	System	04 Jan 2021 16:53:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:33
User entered empty.	System	04 Jan 2021 16:53:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 17:12:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:12:29
Data point term sent to Coder	System	04 Jan 2021 16:55:50
User entered 'dextrose 50%'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hypoglycemia'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:55:01
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:55:01
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:55:01

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:55:01
	(b) (4)	



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '18 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:55:01

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:01

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
User entered empty.	System	04 Jan 2021 16:55:01

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
User entered empty.	System	04 Jan 2021 16:55:01

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:53
User entered empty.	System	04 Jan 2021 16:55:01



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:22:57
Data point term sent to Coder	System	26 Feb 2021 18:24:25
Coding entries removed.	(b) (4), (b) (6)	26 Feb 2021 18:23:35
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 00:54:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 00:54:39
Data point term sent to Coder	System	04 Jan 2021 16:56:51
User entered 'ativan'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query ""	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:40:45
Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF." ' (Site from DM).		
Query ""	(b) (4), (b) (6)	26 Feb 2021 18:24:25
Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF." ' answered with 'Indication corrected to match AE reported. ' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 18:23:35
User entered 'episodes of AGITATION' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:23:35
User opened query ""	(b) (4), (b) (6)	11 Feb 2021 11:09:12
Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF." ' (Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'agitation'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 06:44:10
Query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'No other information is given according to medical records. Correct as entered' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:58:59
User opened query 'Per DM CLR: Please provide the actual dose for this medication in Milligrams instead of number of Milliliters as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:20:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0.5'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mL (mL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:55:54
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once (ONCE)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:55:54
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:55:54
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:55:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
User entered empty.	System	04 Jan 2021 16:55:54



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
User entered empty.	System	04 Jan 2021 16:55:54

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:00
User entered empty.	System	04 Jan 2021 16:55:54

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:41
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:58:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:58:44
Data point term sent to Coder	System	02 Mar 2021 17:58:19
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 17:58:16
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:44
Data point term sent to Coder	System	04 Jan 2021 16:57:53
User entered 'magnesium sulfate'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

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EAB) (1725)

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US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 03:17:23
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	02 Mar 2021 17:58:48
' answered with 'New AE has been added matching indication of ConMed. ' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	02 Mar 2021 17:58:16
User entered 'Hypomagnesemia' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 17:58:16
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 11:57:33
' (Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'magnesium replacement'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:56:55
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 2 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:56:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '19 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '19 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:56:55



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:56:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
User entered empty.	System	04 Jan 2021 16:56:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
User entered empty.	System	04 Jan 2021 16:56:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:04
User entered empty.	System	04 Jan 2021 16:56:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 18:10:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:10:30
Data point term sent to Coder	System	04 Jan 2021 16:59:55
User entered 'hydromorphone'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'right ankle pain'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0.5'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:59:30
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 4 hours as needed'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 16:59:30
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '20 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 16:59:30



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '21 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 16:59:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
User entered empty.	System	04 Jan 2021 16:59:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
User entered empty.	System	04 Jan 2021 16:59:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:10
User entered empty.	System	04 Jan 2021 16:59:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN;SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:42:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:42:15
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMPICILLIN SODIUM;SULBACTAM SODIUM, PRODUCTSYNONYM: AMPICILLIN/SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 17:02:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 17:02:28
Data point term sent to Coder	System	04 Jan 2021 17:01:56
User entered 'ampicillin/sulbactam'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'sepsis'	Junlin Long (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '3'	Junlin Long (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:01:30
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 6 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 17:01:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 17:01:30



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '20 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '23 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:01:30

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:01:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
User entered empty.	System	04 Jan 2021 17:01:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
User entered empty.	System	04 Jan 2021 17:01:30

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:17
User entered empty.	System	04 Jan 2021 17:01:30



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:01:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 12:01:38
Data point term sent to Coder	System	03 Mar 2021 14:11:50
Coding entries removed.	(b) (4), (b) (6)	03 Mar 2021 14:11:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:29:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:29:44
Data point term sent to Coder	System	02 Mar 2021 18:29:09
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 18:29:06
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:03:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:03:44
Data point term sent to Coder	System	04 Jan 2021 17:03:58
User entered 'potassium chloride er'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR re-query: Response noted. However, there is no corresponding AE recorded within the timeframe of this conmed. Please note AE #23"Hypokalemia" recorded with the start date 17NOV2020 and stop date 18NOV2020. Please reconcile and update for appropriate match, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 08:55:51
Query 'Per DM CLR re-query: Response noted. However, there is no corresponding AE recorded within the timeframe of this conmed. Please note AE #23"Hypokalemia" recorded with the start date 17NOV2020 and stop date 18NOV2020. Please reconcile and update for appropriate match, else clarify.' answered with 'New AE has been added. This medication was given for a 3rd episode of Hypokalemia.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:11:48
User entered 'HYPOKALEMIA (3rd episode)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 14:11:37
User opened query 'Per DM CLR re-query: Response noted. However, there is no corresponding AE recorded within the timeframe of this conmed. Please note AE #23"Hypokalemia" recorded with the start date 17NOV2020 and stop date 18NOV2020. Please reconcile and update for appropriate match, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:34:47
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:19:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'New AE has been added to match this ConMed indication.' (Site from DM). Signature has been broken.	(b) (4), (b) (6) (b) (4)	02 Mar 2021 18:29:29
	(b) (4), (b) (6)	02 Mar 2021 18:29:06
User entered 'Hypokalemia' reason for change: Per Query Resolution	(b) (4), (b) (6) (b) (4)	02 Mar 2021 18:29:06
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	11 Feb 2021 11:57:09
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User entered 'potassium replacement'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '20'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'meq'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every2 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:03:02
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '23 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '23 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:03:02



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
User entered empty.	System	04 Jan 2021 17:03:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
User entered empty.	System	04 Jan 2021 17:03:02

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:22
User entered empty.	System	04 Jan 2021 17:03:02

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: POTASSIUM;SODIUM PHOSPHATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 11:50:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 11:50:32
Data point term sent to Coder	System	03 Mar 2021 14:14:59
Data point term sent to Coder	System	02 Mar 2021 19:07:59
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 19:07:23
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: OTHER MINERAL PRODUCTS, PRODUCT: POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:53:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:53:43
Data point term sent to Coder	System	04 Jan 2021 17:07:01
User entered 'potassium sodium phosphates (2 pks)'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR re-query: Response noted. However, there is no corresponding AE recorded within the timeframe of this conmed. Please note AE #23"Hypokalemia" recorded with the start date 17NOV2020 and stop date 18NOV2020. Please reconcile and update for appropriate match, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 08:56:13
Query 'Per DM CLR re-query: Response noted. However, there is no corresponding AE recorded within the timeframe of this conmed. Please note AE #23"Hypokalemia" recorded with the start date 17NOV2020 and stop date 18NOV2020. Please reconcile and update for appropriate match, else clarify.' answered with 'New AE has been added. This medication was given for a 3rd episode of Hypokalemia.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:14:25
User entered 'HYPOKALEMIA (3rd episode)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 14:14:18
User opened query 'Per DM CLR re-query: Response noted. However, there is no corresponding AE recorded within the timeframe of this conmed. Please note AE #23"Hypokalemia" recorded with the start date 17NOV2020 and stop date 18NOV2020. Please reconcile and update for appropriate match, else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:35:15
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:35:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.  ' answered with 'Indication has been updated to match current AE.' (Site from DM). Signature has been broken.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 19:07:59
User entered 'hypokalemia' reason for change: Per Query Resolution	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 19:07:23
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Susanne Doblecki-Lewis (b) (4)	11 Feb 2021 11:55:28 14 Jan 2021 15:15:29
User entered 'electrolyte replacement'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '2'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'packs'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated as the Medication was given for 1 day duration only. Update eCRF as appropriate. Else, provide a comment.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:29:51
Query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated as the Medication was given for 1 day duration only. Update eCRF as appropriate. Else, provide a comment.' answered with 'Participant received the dose 3 times in 24 hour hours. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:34:09
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:33:17
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:33:17
User opened query 'Per DM CLR: Please review the frequency and confirm if this should be changed/updated as the Medication was given for 1 day duration only. Update eCRF as appropriate. Else, provide a comment.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:34:11
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'three times daily (TID)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'THREE TIMES in 24 hours' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:34:20
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:33:17
User entered 'Three times that day' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:33:17
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:06:03
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '23 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:06:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '23 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:06:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
User entered empty.	System	07 Apr 2021 16:33:17
User entered '3'	System	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:10:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
User entered empty.	System	07 Apr 2021 16:33:17
User entered '1'	System	04 Jan 2021 17:06:03

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:30
User entered empty.	System	07 Apr 2021 16:33:17
User entered '804 (804)'	System	04 Jan 2021 17:06:03

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 18:42:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:42:30
Data point term sent to Coder	System	04 Jan 2021 17:08:02
User entered 'lidocaine 4% patch'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'right ankle pain'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:07:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'patch'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once daily (QD)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:07:36
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Transdermal (TRANSDERMAL)'	Junlin Long (b) (4)	04 Jan 2021 17:07:36

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:07:36
	(b) (4)	



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '24 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:07:36

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:07:36

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:07:36

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
User entered '1'	System	04 Jan 2021 17:07:36

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
User entered '1'	System	04 Jan 2021 17:07:36

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:33
User entered '804 (804)'	System	04 Jan 2021 17:07:36



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 17:11:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 17:11:30
Data point term sent to Coder	System	04 Jan 2021 17:10:13
User entered 'polyethylene glycol'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	08 Mar 2021 04:50:50
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	05 Mar 2021 16:22:15
' answered with 'New AE was added to match this ConMed.'		
' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	11 Feb 2021 11:54:57
' (Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered 'constipation'	Junlin Long (b) (4)	04 Jan 2021 17:09:19
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '17'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:09:19
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once daily (QD)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:09:19
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:09:19
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '24 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:09:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
User entered '1'	System	04 Jan 2021 17:09:19



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
User entered '1'	System	04 Jan 2021 17:09:19

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:37
User entered '804 (804)'	System	04 Jan 2021 17:09:19

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:40:49
	(b) (4)	
Data point term sent to Coder	System	04 Jan 2021 17:11:14
User entered 'senna - docusate'	Junlin Long (b) (4)	04 Jan 2021 17:10:50
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	08 Mar 2021 04:52:13
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	05 Mar 2021 16:22:34
' answered with 'New AE was added to match this ConMed.' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	11 Feb 2021 11:54:33
' (Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered 'constipation'	Junlin Long (b) (4)	04 Jan 2021 17:10:50
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 50/8.6).' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:04:37
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
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., 50/8.6).' answered with 'Missing dose component has been entered.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:28:52
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 16:28:25
User entered '8.6/50' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:28:25
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., 50/8.6).' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:54:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '8.6'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:10:50
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'twice daily (BID)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:10:50
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:10:50
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '24 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:10:50



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:10:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
User entered '2'	System	04 Jan 2021 17:10:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
User entered '1'	System	04 Jan 2021 17:10:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:40
User entered '804 (804)'	System	04 Jan 2021 17:10:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: FATTY ACID DERIVATIVES, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DIVALPROEX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 17:30:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:30:29
Data point term sent to Coder	System	04 Jan 2021 17:12:15
User entered 'divalproex dr'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SEIZURES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:48:11
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SEIZURES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:48:05
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'seizures'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '125'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:12:12
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'twice daily (BID)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:12:12
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:12:12
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEIZURES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:06:08
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEIZURES should be recorded, and update con med indication or provide clarification. ' answered with 'Participant has been taking Depakote (Divalproex DR) 500mg since year 2000 for seizures. This is not a worsening AE as this is half her usual dose. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:41:46
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEIZURES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:51:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '6 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:37:31
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:37:31
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '11 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:12:12

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
User entered '2'	System	04 Jan 2021 17:12:12

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
User entered '1'	System	04 Jan 2021 17:12:12

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:45
User entered '804 (804)'	System	04 Jan 2021 17:12:12

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 21:22:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:22:41
Data point term sent to Coder	System	04 Jan 2021 17:15:18
User entered 'narcans'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:14:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:14:59



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'lethargy - suspected opioid abuse'	Junlin Long (b) (4)	04 Jan 2021 17:14:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0.4'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:14:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:14:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:14:59
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once (ONCE)'	Junlin Long (b) (4)	04 Jan 2021 17:14:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:14:59
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:14:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'unknown'	Junlin Long (b) (4)	04 Jan 2021 17:14:59



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '10 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:14:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:14:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:14:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '10 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:14:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:14:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
User entered empty.	System	04 Jan 2021 17:14:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
User entered empty.	System	04 Jan 2021 17:14:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:49
User entered empty.	System	04 Jan 2021 17:14:59



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: FATTY ACID DERIVATIVES, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DIVALPROEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 17:45:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:45:29
Data point term sent to Coder	System	04 Jan 2021 17:16:18
User entered 'divalproex dr'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'seizures'	Junlin Long (b) (4)	04 Jan 2021 17:15:56

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '500'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:15:56
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'twice daily (BID)'	Junlin Long (b) (4)	04 Jan 2021 17:15:56

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:15:56
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:15:56
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '11 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:15:56

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:15:56

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '17 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:15:56

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
User entered '2'	System	04 Jan 2021 17:15:56



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
User entered '1'	System	04 Jan 2021 17:15:56

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:53
User entered '804 (804)'	System	04 Jan 2021 17:15:56

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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: ELECTROLYTES NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:41:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:41:40
Data point term sent to Coder	System	05 Mar 2021 16:07:30
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 16:07:24
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: ELECTROLYTES NOS, PRODUCTSYNONYM: ELECTROLYTE SOLUTIONS [ELECTROLYTES NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:42:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:42:36
Data point term sent to Coder	System	04 Jan 2021 17:18:19
User entered 'electrolyte - a infusion'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:10:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Indication was added to match new AE. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:08:42
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 16:07:24
User entered 'Electrolyte Imbalance' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 16:07:24
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:41:57
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'volume and electrolyte replacement'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '125'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mL (mL)'	Junlin Long (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:18:07
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'continuous'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:18:07
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '12 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '12 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:18:07



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:18:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
User entered empty.	System	04 Jan 2021 17:18:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
User entered empty.	System	04 Jan 2021 17:18:07

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:47:57
User entered empty.	System	04 Jan 2021 17:18:07

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:10:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:10:47
Data point term sent to Coder	System	03 Mar 2021 14:29:32
Coding entries removed.	(b) (4), (b) (6)	03 Mar 2021 14:29:28
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:39:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:39:30
Data point term sent to Coder	System	04 Jan 2021 17:21:20
User entered 'lidocaine 1%'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Con Proc eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 04:26:38
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Con Proc eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Medication was used for the Lumbar Puncture procedure performed. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:33:33
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 14:29:28
User entered 'Lumbar Puncture' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 14:29:28
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Con Proc eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:40:51
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'local anesthesia'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:20:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '10'	Junlin Long	04 Jan 2021 17:20:38



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mL (mL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once (ONCE)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'intradermal'	Junlin Long (b) (4)	04 Jan 2021 17:20:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '15 Nov 2020'	Junlin Long	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long	04 Jan 2021 17:20:38



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:20:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '15 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:20:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:20:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:20:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:20:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 20:02:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 20:02:30
Data point term sent to Coder	System	04 Jan 2021 17:22:23
User entered 'rivaroxaban'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Jan 2021 17:21:42



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'dvt prophylaxis'	Junlin Long	04 Jan 2021 17:21:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '20'	Junlin Long	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once daily (QD)'	Junlin Long	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:21:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	Junlin Long	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 17:21:42



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	Junlin Long	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '17 Nov 2020'	Junlin Long	04 Jan 2021 17:21:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:21:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 17:21:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 17:21:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 17:21:42



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE 5% - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 17:12:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:12:28
Data point term sent to Coder	System	04 Jan 2021 17:23:23
User entered 'dextrose 5%'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hypoglycemia'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25'	Junlin Long (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:22:46
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:22:46
	(b) (4)	



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:22:46
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '16 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '18 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:22:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
User entered empty.	System	04 Jan 2021 17:22:46



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
User entered empty.	System	04 Jan 2021 17:22:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:28
User entered empty.	System	04 Jan 2021 17:22:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 20:02:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 20:02:31
Data point term sent to Coder	System	04 Jan 2021 17:25:26
User entered 'quetiapine'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'paranoia'	Junlin Long (b) (4)	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '400'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:24:42
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once daily (QD)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:24:42
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Jan 2021 17:24:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:24:42
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening PARANOIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:13:40
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening PARANOIA should be recorded, and update con med indication or provide clarification. ' answered with 'Due to participant being admitted on 11/6/2020, her current Paranoia medication Seroquel (Quetiapine) was stopped upon admission. It was given once in the hospital and participant restarted the medication once discharged. She restarted the medication on 11/26/2020.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:26:26
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening PARANOIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:30:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '17 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:24:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:24:42



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:24:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered '1'	System	04 Jan 2021 17:24:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered '1'	System	04 Jan 2021 17:24:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:32
User entered '804 (804)'	System	04 Jan 2021 17:24:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:15:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:15:27
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:19:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:19:01
Data point term sent to Coder	System	05 Mar 2021 15:28:21
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 15:27:42
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:44
Data point term sent to Coder	System	04 Jan 2021 17:27:31
User entered 'magnesium sulfate'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:15:55
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'Indication updated to match AE.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:28:15
User entered 'HYPOMAGNESEMIA (2nd Episode)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 15:27:59
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 15:27:42
User entered 'Hypomagnesemia' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 15:27:42
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:28:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'magnesium replacement'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:26:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:26:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 2 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 17:26:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:26:55
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '21 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '21 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:26:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:26:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
User entered empty.	System	04 Jan 2021 17:26:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
User entered empty.	System	04 Jan 2021 17:26:55

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:37
User entered empty.	System	04 Jan 2021 17:26:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:44:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:44:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 16:39:52 07 Apr 2021 16:39:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:03:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:03:53
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Mar 2021 15:44:47 05 Mar 2021 15:44:09
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:08:29

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Jan 2021 17:08:29
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Jan 2021 17:30:33
User entered 'd5w 0.45 ns'	Junlin Long (b) (4)	04 Jan 2021 17:30:15
	(b) (4)	



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 16:39:29
User entered 'Unknown' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 16:39:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:44:09
User entered 'HYPOTENSION (1st episode) and Hypotension (2nd episode)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 15:44:09
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hypotension'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '100'	Junlin Long	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mL (mL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'continuous'	Junlin Long (b) (4)	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 17:30:15



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR RQ: Response noted. However, AE "Hypotension" 1st episode start date is "06NOV2020" and stop date is "13NOV2020" and the 2nd episode start date is "21NOV2020" and stop date is "23NOV2020". Conmed start date is "19NOV2020". So please reconcile and update the conmed start date for the appropriate match, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:42:34
Query 'Per DM CLR RQ: Response noted. However, AE "Hypotension" 1st episode start date is "06NOV2020" and stop date is "13NOV2020" and the 2nd episode start date is "21NOV2020" and stop date is "23NOV2020". Conmed start date is "19NOV2020". So please reconcile and update the conmed start date for the appropriate match, else clarify.' answered with 'Given that them medical records do not provide sufficient information on and the dates do not overlap with any of the 2 hypotension episodes. I have updated the indication to unknown. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:43:38
User opened query 'Per DM CLR RQ: Response noted. However, AE "Hypotension" 1st episode start date is "06NOV2020" and stop date is "13NOV2020" and the 2nd episode start date is "21NOV2020" and stop date is "23NOV2020". Conmed start date is "19NOV2020". So please reconcile and update the conmed start date for the appropriate match, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:29:47
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE ( START DATE 21 NOV 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:29:47

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE ( START DATE 21 NOV 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify. ' answered with 'This medication was given for 1st and 2nd episode of Hypotension. AE start date was corrected.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:45:18
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE ( START DATE 21 NOV 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:25:57
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '19 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long	04 Jan 2021 17:30:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:30:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '24 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:30:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:30:15



US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:30:15

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:30:15

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:50:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:28:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:28:24
Data point term sent to Coder	System	05 Mar 2021 15:40:37
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 15:39:39
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:43:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:43:34

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	04 Jan 2021 17:32:36
User entered 'normal saline'	Junlin Long (b) (4)	04 Jan 2021 17:31:39
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:39:39
User entered 'HYPOTENSION (1st episode) and Hypotension (2nd episode)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 15:39:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hypotension'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '1-2'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mL (mL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:31:39
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:31:39

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'as ordered for significant hypotension'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Junlin Long (b) (4)	04 Jan 2021 17:31:39

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:31:39
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE#12 (START DATE 21 NOV 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:22:41
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE#12 ( START DATE 21 NOV 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify ' answered with 'Participant's 1st episode of Hypotension started on 11/06/2020 and 2nd episode started 11/21/2020 therefore this medication was given primarily for 1st episode of Hypotension and overlapped to 2nd episode.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:42:14
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE#12 (START DATE 21 NOV 2020). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:25:17
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '10 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:31:39

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '22 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:31:39

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:31:39

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
User entered empty.	System	04 Jan 2021 17:31:39

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
User entered empty.	System	04 Jan 2021 17:31:39

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:59
User entered empty.	System	04 Jan 2021 17:31:39

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:15:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:15:27
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:19:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:19:02
Data point term sent to Coder	System	05 Mar 2021 15:29:21
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 15:29:09
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:45
Data point term sent to Coder	System	04 Jan 2021 17:33:37
User entered 'magnesium sulfate'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:24:14
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'Indication updated to match AE' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:29:25
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 15:29:09
User entered 'Hypomagnesemia (2nd Episode)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 15:29:09
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:22:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'magnesium replacement'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:32:45
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:32:45

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'every 2 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 17:32:45

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:32:45
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '23 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:32:45



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:32:45

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '23 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:32:45

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:32:45

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
User entered empty.	System	04 Jan 2021 17:32:45

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
User entered empty.	System	04 Jan 2021 17:32:45

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:33
User entered empty.	System	04 Jan 2021 17:32:45

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: MAGNETIC RESONANCE IMAGING CONTRAST MEDIA, ATC: PARAMAGNETIC CONTRAST MEDIA, PRODUCT: MEGLUMINE GADOTERATE, PRODUCTSYNONYM: DOTAREM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:48:54
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 Mar 2021 15:48:54
Data point term sent to Coder	System	05 Mar 2021 15:47:49
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 15:47:37
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:15:29
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: MAGNETIC RESONANCE IMAGING CONTRAST MEDIA, ATC: PARAMAGNETIC CONTRAST MEDIA, PRODUCT: MEGLUMINE GADOTERATE, PRODUCTSYNONYM: DOTAREM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 17:35:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 17:35:35
Data point term sent to Coder	System	04 Jan 2021 17:34:37
User entered 'dotarem'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:34:26



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:25:58
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Indication has been updated to reflect the reason for this medication. This medication was given to perform a diagnostic procedure listed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:50:29
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 15:47:37
User entered 'MRI right ankle with and without contrast' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 15:47:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:22:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'iv contrast'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:34:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'unknown'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'unknown'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once (ONCE)'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:34:26
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	04 Jan 2021 17:34:26



US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:34:26
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '24 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:34:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '24 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long (b) (4)	04 Jan 2021 17:34:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
User entered empty.	System	04 Jan 2021 17:34:26

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
User entered empty.	System	04 Jan 2021 17:34:26



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:07
User entered empty.	System	04 Jan 2021 17:34:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ABACAVIR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 17:36:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 17:36:29
Data point term sent to Coder	System	04 Jan 2021 17:35:38
User entered 'abacavir'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:35:14

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long	04 Jan 2021 17:35:14

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hiv'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:35:14

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '600'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:35:14

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Jan 2021 17:35:14

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:35:14
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Jan 2021 17:35:14



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:35:14
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Jan 2021 17:35:14

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:35:14
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 05:38:08
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' answered with 'HIV has not worsen. Participant has been on this medication since 2010 for HIV. It was restarted on Nov 22, 2020 while admitted in the hospital.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 18:12:47
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:21:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '22 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:35:14

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:35:14

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:35:14

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:35:14

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:35:14



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
User entered '1'	System	04 Jan 2021 17:35:14

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
User entered '1'	System	04 Jan 2021 17:35:14

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:13
User entered '804 (804)'	System	04 Jan 2021 17:35:14

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: LAMIVUDINE - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Jan 2021 17:37:29
Data point term sent to Coder	(b) (4)	
User entered 'lamivudine'	System	04 Jan 2021 17:36:39
	Junlin Long (b) (4)	04 Jan 2021 17:36:21
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	Junlin Long (b) (4)	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hiv'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '300'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:36:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Jan 2021 17:36:21



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:36:21
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 17:36:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	04 Jan 2021 17:36:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:36:21
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:28:03
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' answered with 'Participant was on Triumeq prior to admission and was stopped upon admission. This is a combination drug of Abacavir, dolutegravir, and lamivudine. This is not worsening HIV since this medication is a current medication the participant takes. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:54:38
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:20:48
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '22 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	Junlin Long (b) (4)	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:36:21



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:36:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
User entered '1'	System	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
User entered '1'	System	04 Jan 2021 17:36:21

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:23
User entered '804 (804)'	System	04 Jan 2021 17:36:21

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: OTHER ANTIVIRALS, PRODUCT: DOLUTEGRAVIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 17:38:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 17:38:30
Data point term sent to Coder	System	04 Jan 2021 17:37:39
User entered 'dolutegravir'	Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'hiv'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '50'	Junlin Long (b) (4)	04 Jan 2021 17:37:06

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:37:06
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Jan 2021 17:37:06

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:37:06
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	04 Jan 2021 17:37:06
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:30:39
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' answered with 'This is not worsening HIV since participant already takes this medication prior to admission.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:56:02
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HIV should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:17:28
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '22 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:37:06

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	04 Jan 2021 17:37:06

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered '1'	System	04 Jan 2021 17:37:06

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered '1'	System	04 Jan 2021 17:37:06

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:34
User entered '804 (804)'	System	04 Jan 2021 17:37:06

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
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.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 14:33:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 14:33:58
Data point term sent to Coder	System	16 Feb 2021 14:33:22
User entered 'tylenol'	Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, MUSCLE ACHES, JOINT ACHES, CHILLS, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, MUSCLE ACHES, JOINT ACHES, CHILLS, FEVER did not meet the AE reporting criteria. Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 11. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:27:23

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, MUSCLE ACHES, JOINT ACHES, CHILLS, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, MUSCLE ACHES, JOINT ACHES, CHILLS, FEVER did not meet the AE reporting criteria. Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 11. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.' answered with 'Participant reported those symptoms in diary dose 1-General Day. Those symptoms have not been reported to AE log as per protocol section 8.3.4. ConMed #11 has different indication and start/stop date from this AE. As a result did not combine them together. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:43:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, MUSCLE ACHES, JOINT ACHES, CHILLS, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, MUSCLE ACHES, JOINT ACHES, CHILLS, FEVER did not meet the AE reporting criteria. Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 11. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	09 Mar 2021 06:19:27
	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
	(b) (4)	
User entered 'headaches, muscle aches, joint aches, chills, fever'	Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '500'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Feb 2021 14:32:37
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Feb 2021 14:32:37
	(b) (4)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Feb 2021 14:32:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '21 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '22 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Feb 2021 14:32:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Feb 2021 14:32:37



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User entered empty.	System	16 Feb 2021 14:32:37

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User entered empty.	System	16 Feb 2021 14:32:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User entered empty.	System	16 Feb 2021 14:32:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:47:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:47:39
	(b) (4)	
Data point term sent to Coder	System	07 Apr 2021 17:46:44
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 17:45:45
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:45:45
	(b) (4), (b) (6)	
User entered 'TRiUMEQ' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:45:45
	(b) (4), (b) (6)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 12:41:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 12:41:34
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 18:36:37
User entered 'TRUMEQ'	(b) (4), (b) (6)	22 Feb 2021 18:35:38
	(b) (4), (b) (6)	

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'HIV'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:10:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please update the dose to include both components using slash (e.g. 5/325) and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:26:53
Query 'Per DM CLR: Please update the dose to include both components using slash (e.g. 5/325) and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' answered with 'Dose updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:45:11
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 17:44:57
User entered '600/50/300' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 17:44:57
User opened query 'Per DM CLR: Please update the dose to include both components using slash (e.g. 5/325) and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:19:42
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '1 TAB(350MG/150MG/75MG)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 18:35:38

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 18:35:38

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ANXIETY worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:26:45
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ANXIETY worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'Participant has been taking this medication since year 2000. It was interrupted upon admission. It is not worsening Anxiety. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:48:19
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ANXIETY worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:19:50
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 18:53:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:53:02
Data point term sent to Coder	System	22 Feb 2021 18:52:08
User entered 'DEPAKOTE'	(b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'ANXIETY'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '500'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:10:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 18:51:32

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 18:51:40
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		22 Feb 2021 18:51:32
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 18:51:32

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 18:51:32

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 19:11:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 19:11:01
Data point term sent to Coder	System	22 Feb 2021 19:10:31
User entered 'SEROQUEL'	(b) (4), (b) (6)	22 Feb 2021 19:09:50



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'PARANOIA'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '400'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
User entered '1'	System	22 Feb 2021 19:09:50

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
User entered '1'	System	22 Feb 2021 19:09:50



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
User entered '804 (804)'	System	22 Feb 2021 19:09:50

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
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.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 19:15:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 19:15:02
Data point term sent to Coder	System	22 Feb 2021 19:14:37
User entered 'XARELTO'	(b) (4), (b) (6)	22 Feb 2021 19:13:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'PROPHYLAXIS FOR DVT'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '10'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:13:59



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
User entered '1'	System	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
User entered '1'	System	22 Feb 2021 19:13:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (81)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:34
User entered '804 (804)'	System	22 Feb 2021 19:13:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE, PRODUCTSYNONYM: PULMICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 05:03:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 05:03:00
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 22:02:44
Data point term sent to Coder	System	02 Mar 2021 19:33:21
User entered 'Budesonide (Pulmicort)'	(b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Asthma'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '0.25'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 19:32:40

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 19:32:40

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
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) (b) (4)	08 Apr 2021 09:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:51:48
Data point term sent to Coder	System	07 Apr 2021 14:35:10
User entered 'Supplemental O2 VIA NASAL CANNULA'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Unknown'	(b) (4), (b) (6)	07 Apr 2021 14:34:59



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'unknown'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '2L'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'other (OTHER)'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Continuous'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '06 Nov 2020'	(b) (4), (b) (6)	07 Apr 2021 14:34:59



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '26 Nov 2020'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User entered empty.	System	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User entered empty.	System	07 Apr 2021 14:34:59

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:44
User entered empty.	System	07 Apr 2021 14:34:59

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:53:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:53:55
Data point term sent to Coder	System	16 Apr 2021 12:52:42
User entered 'tylenol extra strength'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'fever'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '500'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'as needed (PRN)'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '21 Oct 2020'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '22 Oct 2020'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User entered empty.	System	16 Apr 2021 12:52:00

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User entered empty.	System	16 Apr 2021 12:52:00



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:45
User entered empty.	System	16 Apr 2021 12:52:00

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:02:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:02:44
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 14:01:57
User entered 'alprazolam'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'anxiety'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '2'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	16 Apr 2021 14:01:04



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:01:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'un Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:01:04



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 14:01:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:01:04

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (85)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 14:01:04

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:04:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:04:03
Data point term sent to Coder	System	16 Apr 2021 14:03:00
User entered 'metformin'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'diabetes'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '500'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 14:02:57



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'un Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:03:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 14:03:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:03:13
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:02:57
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:02:57



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:02:57

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:02:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:02:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:02:57

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (86)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 14:02:57

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:10:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
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) (b) (4)	16 Apr 2021 14:06:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:06:41
Data point term sent to Coder	System	16 Apr 2021 14:06:03
User entered 'Albuterol Sulfate (proair)'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Asthma'	(b) (4), (b) (6)	16 Apr 2021 14:05:46



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '90'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'MCG'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:05:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'un UNK 2005'	(b) (4), (b) (6)	16 Apr 2021 14:05:46



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:05:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:05:46

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (87)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:05:46

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:00
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 BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:10:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:10:45
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 14:10:06
User entered 'atrovent'	(b) (4), (b) (6)	16 Apr 2021 14:09:42



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'asthma'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '17'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'MCG'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	16 Apr 2021 14:09:42



US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:09:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'UN UNK 2011'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:09:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:09:42

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:09:42



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (88)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:09:42

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:13:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:13:47
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 14:12:08
User entered 'IBUPROFEN'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'RIGHT FOOT PAIN'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '800'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	16 Apr 2021 14:11:37



US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '26 Nov 2020'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:11:44
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		16 Apr 2021 14:11:44
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		16 Apr 2021 14:11:37
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:11:37



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:11:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (89)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:11:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:13:50
Data point term sent to Coder	System	16 Apr 2021 14:13:09
User entered 'TYLENOL EXTRA STRENGTH'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'FEVER'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '500'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 14:12:58



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:10:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '21 Oct 2020'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:12:58



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '22 Oct 2020'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 10 Jun 2021 09:10:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:13:21
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User entered empty.	System	16 Apr 2021 14:12:58

US3622282

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User entered empty.	System	16 Apr 2021 14:12:58

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (90)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:52
User entered empty.	System	16 Apr 2021 14:12:58

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:10:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICILLIN/CLAVULANIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:38:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:38:08
Data point term sent to Coder	System	21 Apr 2021 12:36:48
User entered 'amoxicillin/clavulanic acid'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:10:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'right ankle cellulitis'	(b) (4), (b) (6)	21 Apr 2021 12:36:37



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'unknown'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Unknown'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 10 Jun 2021 09:10:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '25 Jan 2021'	(b) (4), (b) (6)	21 Apr 2021 12:36:37



**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered '03 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 16:19:26
User entered '09 Feb 2021'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:45:00
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User entered '2'	System	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User entered '1'	System	21 Apr 2021 12:36:37

**US3622282**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (91)**

**Generated On: 10 Jun 2021 09:10:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:57
User entered '804 (804)'	System	21 Apr 2021 12:36:37

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:10:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:26
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:27:06



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Signature has been broken.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:23:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:56:42

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'chest x ray'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:56:42

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:56:42

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:56:42

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:46:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:57:16

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:46:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'right foot x ray'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:57:16

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:46:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:57:16

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:46:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:57:16



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:02
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:58:00

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:02
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'right ankle x ray'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:58:00

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:02
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:58:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:02
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:58:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:00

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'ct tib-fib right with iv contrast'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:00



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:33

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'electrocardiogram (ekg)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:33

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:33

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 18:59:33

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '6 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:03:55

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'ultrasound bilateral upper extremities'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:03:55

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:03:55

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:14
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:03:55



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '10 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:04:53

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'ct brain without iv contrast'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:04:53

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:04:53

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:04:53

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:22
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '10 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:05:11

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:22
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'mri brain without iv contrast'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:05:11

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:22
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:05:11

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:22
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:05:11



**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:08

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 15:11:31
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 15:11:31
User entered 'Mid LINE INSERTION - ULTRASOUND GUIDED' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 15:11:31
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'picc line insertion - ultrasound guided'	Junlin Long (b) (4)	09 Dec 2020 19:07:08

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Adverse Event (AE)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:08

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:08

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:31
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:39

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:31
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'ct abd/pelvis without iv contrast'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:39

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:31
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:39

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:31
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:39



**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (11)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '12 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:55

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'chest x ray'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:55

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:55

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (11)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:07:55

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (12)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:08:33

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'portable eeg'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:08:33

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:08:33

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:08:33



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:03

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'bedside eeg monitoring continuous'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:03

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:03

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:03

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '11 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:26

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'transthoracic echo'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:26

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:26

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:26



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '15 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:50

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'lumbar puncture'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:50

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:50

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:09:50

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:53
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '16 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:04

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:53
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'chest x ray'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:04

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (16)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:53
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:04

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:53
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:04



**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (17)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered '17 Nov 2020'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:27

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'ct brain without iv contrast'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:27

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (17)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:27

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (17)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:47:56
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:51:19
User entered empty.	Junlin Long (b) (4) (b) (4)	09 Dec 2020 19:10:27

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (18)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '21 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:39:40

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'chest x ray'	Junlin Long (b) (4)	04 Jan 2021 17:39:40

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Jan 2021 17:39:40

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 17:39:40



**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (19)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '22 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:40:05

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'chest x ray'	Junlin Long (b) (4)	04 Jan 2021 17:40:05

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Jan 2021 17:40:05

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 17:40:05

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '24 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:40:40

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'mri right ankle with and without iv contrast'	Junlin Long (b) (4)	04 Jan 2021 17:40:40

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Jan 2021 17:40:40

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 17:40:40



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:41:13

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'us dvt upper bilateral extremities'	Junlin Long (b) (4)	04 Jan 2021 17:41:13

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Jan 2021 17:41:13

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 17:41:13

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '25 Nov 2020'	Junlin Long (b) (4)	04 Jan 2021 17:41:39

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'us dvt lower bilateral extremities'	Junlin Long (b) (4)	04 Jan 2021 17:41:39

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (22)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Jan 2021 17:41:39

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered empty.	Junlin Long (b) (4)	04 Jan 2021 17:41:39



**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (23)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:35:57

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Blood Culture'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:35:57

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (23)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:35:57

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:35:57

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (24)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:55

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Arterial Blood Gases'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:55

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (24)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:55

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:55



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:14:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Urinalysis'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:14:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (25)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:14:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (25)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:14:00

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:16:00

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'C-Reactive Protein'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:16:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (26)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:16:00

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (26)**

**Generated On: 10 Jun 2021 09:10:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:48:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:16:00



**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (27)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:19:26

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Complete Blood Count and Differential	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:19:26

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (27)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:19:26

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:19:26

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (28)**

**Generated On: 10 Jun 2021 09:10:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:20:07

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Complete Metabolic Panel'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:20:07

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (28)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:20:07

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:49:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:20:07



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '17 Nov 2020'	(b) (4), (b) (6)	02 Mar 2021 17:04:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Mar 2021 17:04:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	25 Feb 2021 15:23:04

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Complete Metabolic Panel'	(b) (4), (b) (6)	02 Mar 2021 17:04:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Mar 2021 17:04:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	25 Feb 2021 15:23:04

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:10:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:04:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Mar 2021 17:04:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	25 Feb 2021 15:23:04

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:04:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Mar 2021 17:04:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	25 Feb 2021 15:23:04

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:23:34

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 09:10:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Magnesium Bloodwork'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:23:34

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (30)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:23:34

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:23:34



US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 09:10:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:24:07

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Magnesium Bloodwork'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:24:07

**US3622282**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (31)**

**Generated On: 10 Jun 2021 09:10:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:24:07

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 09:10:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:50:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:24:07

**US3622282**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 10 Jun 2021 09:10:09**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '8 Dec 2020'	Junlin Long (b) (4)	09 Dec 2020 13:46:59

US3622282

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:10:09

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'Other (OTHER)'	Junlin Long (b) (4)	09 Dec 2020 13:46:59

US3622282

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:10:09

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:05:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered 'unable to comply with protocol visit requirements for second vaccination'	Junlin Long (b) (4)	09 Dec 2020 13:46:59

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
User entered '19/Nov/2020 18:59'	System	19 Nov 2020 18:59:14



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
User entered '09/Dec/2020 13:03'	System	09 Dec 2020 19:03:35

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 19:03:35

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	System	19 Nov 2020 18:59:07
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
User entered '10/Dec/2020 17:40'	System	10 Dec 2020 17:40:02

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:46:07
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 11:48:59
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 17:40:02

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
User entered '05/Jan/2021 11:46'	(b) (4) System	05 Jan 2021 16:46:19

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:46:22
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 16:46:19

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered '27/Jan/2021 13:09'	(b) (4) System	27 Jan 2021 18:09:24



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:56:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:09:24

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '22/Feb/2021 15:56'	(b) (4) System	22 Feb 2021 20:56:32

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 15:39:06
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:56:32

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	15 Dec 2020 11:48:59
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '24/Feb/2021 10:38'	(b) (4) System	24 Feb 2021 15:39:02

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:39:06
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 15:39:02

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	System	19 Nov 2020 18:59:07
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '01/Mar/2021 10:04'	(b) (4) System	01 Mar 2021 15:04:07

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:18:09
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 15:04:07

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4)	15 Dec 2020 11:48:59
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40



**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:19:40
User entered '08/Mar/2021 12:33'	(b) (4) System	08 Mar 2021 17:33:40



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:44:09
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:19:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
Un-reviewed for Safety.	System	09 Dec 2020 19:01:34
User entered 'Yes (Y)'	System	09 Dec 2020 19:01:34
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:48:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:39:28
User entered 'US'	System	19 Nov 2020 18:59:14



US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	21 Apr 2021 20:34:33
User entered '9'	System	08 Mar 2021 17:33:40
User entered '8'	System	01 Mar 2021 15:04:07
User entered '7'	System	24 Feb 2021 15:39:02
Signature has been broken.	System	22 Feb 2021 20:56:32
User entered '6'	System	22 Feb 2021 20:56:32
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:16:52
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 18:09:24
User entered '5'	System	27 Jan 2021 18:09:24
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:15:29
	(b) (4)	
User entered '4'	System	05 Jan 2021 16:46:19
User entered '3'	System	10 Dec 2020 17:40:02
User entered '2'	System	09 Dec 2020 19:03:35
User entered '1'	System	19 Nov 2020 18:59:14

**US3622282**

**Folder: SAE USA-US085-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
	(b) (4)	
User entered '21/Apr/2021 13:34'	System	21 Apr 2021 20:34:33

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:42:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:34:33

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'USA-US085-2021-MRNA-1273-P301000014'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Yes (Y)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Yes (Y)'	System	01 Mar 2021 15:19:06



**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Susanne'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Doblecki-Lewis'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered '1120 NW 14th Street'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Miami'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'FL'	System	01 Mar 2021 15:19:06



**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered '33136'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'US'	(b) (4) System	01 Mar 2021 15:19:44

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 15:19:44

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'USA-US085-2021-MRNA-1273-P301000014'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Yes (Y)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Yes (Y)'	System	01 Mar 2021 15:19:06



**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'No (N)'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Susanne'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Doblecki-Lewis'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered '1120 NW 14th Street'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'Miami'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered 'FL'	System	01 Mar 2021 15:19:06



**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:33
User entered '33136'	System	01 Mar 2021 15:19:06

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'US'	(b) (4) System	01 Mar 2021 15:19:44

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:10:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 15:19:44

**US3622282**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:10:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered '01/Mar/2021 15:19'	(b) (4) System	01 Mar 2021 15:19:44

US3622282

Folder: SAE USA-US085-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:10:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:03:43
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 22:02:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:19:44